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United States Senate

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MEDICAL DEVICES

Early Warning of Problems Is Hampered by Severe Underreporting

ORIGINAL

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GAO

United States
General Accounting Office
Washington, D.C. 20548

Program Evaluation and
Methodology Division

B-223710

December 19, 1986

The Honorable William V. Roth, Jr.
Chairman, Committee on Governmental Affairs
United States Senate

Dear Mr. Chairman:

In response to your request letter of February 26, 1985, this report describes the structure and operation of FDA's postmarketing surveillance system for medical devices and suggests ways to improve these activities. The study examines reporting patterns for adverse events associated with medical devices and actions taken in response to those events prior to the implementation of the mandatory medical-device reporting rule in December 1984.

Our findings suggest the need for a much more concerted effort by the federal government to obtain valid and sufficient postmarketing information. Our report provides baseline data for the evaluation of the effect of the mandatory medical-device reporting requirements.

As we arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of the report. At that time, a copy will be sent to the Secretary of the Department of Health and Human Services. We will also make copies available to interested organizations, as appropriate, and to others upon request.

Sincerely yours,

Eleanor Chelimsky
Director

Executive Summary

Purpose

The Senate Governmental Affairs Committee asked GAO to examine and describe the communications network and its flow patterns for problems associated with medical devices that the Food and Drug Administration (FDA) has reviewed or approved for marketing. With the concurrence of the committee, GAO pursued three study objectives: (1) describe what and how information is reported when problems occur in the use of medical devices, (2) describe how hospitals, manufacturers, and FDA respond to these problems, and (3) review other federal programs that monitor the safety of selected technologies and identify promising practices that FDA might apply to medical devices.

Background

Although FDA reviews or screens medical devices before they are permitted to be marketed, injury-threatening problems may occur after a device is made available and used by the general public. The Medical Device Amendments of 1976 significantly expanded the authority of FDA to oversee the safety and effectiveness of medical devices.

GAO did not attempt to determine the scope of problems associated with all medical devices. The primary issue in GAO's review was whether information about marketed devices that could provide an early warning signal about safety and effectiveness is communicated to device manufacturers and FDA so that timely action can be taken to protect the public from harm.

GAO examined how information about medical-device problems originating in hospitals was communicated outside the hospitals and how device manufacturers and FDA responded to the problems. The review is based on a survey of a nationally representative sample of community hospitals asking about 10 medical devices and the most significant problems associated with their use during 1984.

Results in Brief

From its survey of hospitals, GAO found that 99 percent of the problems associated with the selected devices, including those that could or did cause injury, had not been reported to FDA. FDA's postmarketing surveillance system, which is based on the quantity and quality of the information that flows between device users, manufacturers, independent distributors, and FDA, has several serious flaws directly related to this high level of underreporting. (See page 41.)

Principal Findings

In the GAO survey, hospital personnel indicated awareness of medical-device problems ranging from relatively minor incidents with no adverse effect on patients to an incident associated with the death of a patient.

Types and Major Causes of Problems

For the 10 devices studied, actual injuries were associated with 9 percent of the problems identified. The potential for serious injury or death occurred in 37 percent of the cases. Wear or deterioration of devices was cited as the sole or major cause of problems in about one third of the hospital reports. Other frequently cited causes were defective components, design flaws, and improper use. (See pages 43 and 44.)

Transmission of Problems

Much information about problems with medical devices is not reported outside the hospitals. Of the 1,175 device-associated problems identified in GAO's survey, only 593, or about 51 percent, of the problems were reported to any organization outside the hospital. Furthermore, when the problem involved injury to patients, an outside report was made in less than half the cases. Eighty-three percent of the reports hospitals made were transmitted orally. Thus, reporting was cut in half at the source, and most of what did emerge was not formally documented. (See page 45 and 47.)

The majority of the reports made to organizations outside the hospitals were directed toward the device manufacturers, distributors, and independent distributors. When devices were under a warranty or a service arrangement, the likelihood was high that reports would be made outside the hospital. Problems that were identified as manufacturer-related (such as design flaws) as opposed to user-related (such as errors in the use of a device) had a greater likelihood of being reported outside the hospitals. (See pages 41 and 44.)

Responses to Device Problems

Hospitals took their own actions to avoid a recurrence of 85 percent of the problems. Their most common action was to repair or replace a defective component (33 percent of the cases). For problems reported to manufacturers and distributors, the most common response was the repair or replacement of a failed device (52 percent). Almost no problems were reported to FDA, providing very limited opportunity for FDA to respond. (See pages 54 and 55.)

Weaknesses in the Flow of Information

FDA may not need to know about every problem with devices in hospitals for its postmarketing surveillance activities to be effective. However, an information loss of 99 percent is too high for any effective postmarketing surveillance system. Although GAO's study shows that communication may be adequate to solve individual device problems locally, the system does not provide a clear path along which reports can get to FDA, where much broader actions could be taken. This condition exists despite at least four distinct communications channels to FDA. (See pages 61-63.)

GAO expects the situation to be only slightly improved by a new reporting rule, implemented after the GAO study period, which requires device manufacturers and importers to report to FDA problems that have caused or might cause injury or death. Manufacturers may, as required, report information they possess to FDA; GAO's findings, however, suggest that much information about medical-device problems does not get into the hands of manufacturers. (See pages 49 and 50.)

Limited Use of Problem-Reporting Program

Slightly more than half the health-care professionals surveyed (53 percent) indicated that they were not aware of FDA's system for reporting problems, despite several initiatives by FDA to publicize its existence. (See page 63.)

Promising Practices

The experience of other agencies suggests that representative sampling is an efficient method of obtaining the information necessary to monitor a potentially hazardous technology. (See pages 70 and 71.)

Recommendations

GAO recommends that the secretary of Health and Human Services (HHS) take the following actions to correct the underreporting of medical device problems.

- Independent distributors of medical devices should be required to report information about device problems to manufacturers, as manufacturers are required to report to FDA under the medical-device reporting rule.
- A more effective cooperative relationship should be established with professional health organizations to develop and distribute educational materials for health-care professionals on FDA's need for early warning information and on how to report medical-device problems.

In addition, GAO recommends that FDA explore the possibility of establishing a voluntary, postmarketing surveillance system involving a representative sample of hospitals that would report directly to device manufacturers. This recommendation is made in light of the void of information on problems with medical devices, the potential harm to people that could ensue, and recent developments indicating a more cooperative attitude by hospitals.

Agency Comments

HHS found GAO's draft report to be generally good, indicating that it provides a valuable baseline analysis of reporting on adverse events prior to the initiation of the medical-devices reporting program. According to HHS, GAO's study will enhance evaluations of the effect of the program. While HHS generally agreed with the aims of GAO's recommendations, it implied that the medical-devices reporting program would solve many of the problems GAO found. HHS wants to assess its experience before making any further changes. Although GAO believes the new program may bring some improvement in reporting, the likelihood is that the program will not disclose problems emanating from such segments of the system as hospitals and independent distributors.

Specifically, HHS proposes to continue its evaluation of the medical-devices reporting program before making any implementation decision regarding mandatory reporting by device distributors. GAO believes the need to include distributors in the reporting system has already been demonstrated.

With respect to the recommendation to investigate the feasibility of incorporating a systematic but voluntary hospital reporting program, HHS said that the recommendation was in keeping with FDA's goal but that the GAO approach was problematic. HHS said that the 1980 efforts, in a similar vein, were never fully implemented because hospitals were reluctant to participate and because resources to expand the system were lacking. GAO accepts the agency's comment but disagrees with the assessment of its applicability to today's situation and the consequent feasibility of GAO's recommended approach. GAO found recent evidence that hospitals might be willing to participate and that the costs of the approach might be little more than the costs of the current system or perhaps less, because fewer hospitals might be involved. HHS noted that FDA will assess the reporting program after there is more experience with it. Because hospitals are not required to report their experiences to the manufacturers, however, GAO does not believe that problems with devices will be adequately reported by hospitals under the present system. HHS did not propose a specific course of action with regard to the establishment of a more effective cooperative program with professional health-care organizations. FDA is, however, now looking for other ways to communicate with health-care professionals about the need to report medical-device problems. Other HHS comments and GAO's responses are in chapter 6 and appendix XII.

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Abbreviations

CAT	Computerized axial tomography
CPSC	Consumer Product Safety Commission
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FRA	Federal Railway Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
MSHA	Mine Safety and Health Administration
NASS	National accident sampling system
NEISS	National electronic injury surveillance system
NHTSA	National Highway Traffic Safety Administration
NRC	Nuclear Regulatory Commission
OTA	Office of Technology Assessment
PMAA	Premarketing approval application
USPC	United States Pharmacopeia Convention

Chapter 1

Introduction

It is difficult to conceive of contemporary life without the benefits of modern medical devices. Each year, millions of Americans are treated or otherwise come in contact with medical devices. They are a major factor in maintaining high standards of quality in health care, increasing longevity, and advancing scientific knowledge.

Medical devices run a continuum from the very simple to the extremely complex, from common household items such as thermometers and bandages to kidney dialysis machines and implantable heart valves. Devices such as artificial hips, intraocular lenses, and hearing aids improve the independence and quality of life for many. Diagnostic devices such as CAT (computerized axial tomography) scanners have increased the speed and accuracy of diagnosis and, in some cases, have replaced more dangerous and painful procedures.

Section 201(h) of the Federal Food, Drug, and Cosmetic Act of 1938 as amended by Medical Device Amendments of 1976 defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is

- recognized in the national formulary or the U.S. Pharmacopeia Convention (USPC) or any supplement to them;
- intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in humans or other animals; or
- intended to affect the structure or any function of the human body or the bodies of other animals, and

that does not achieve any of its principal intended purposes through chemical action within or on the body and does not depend upon being metabolized in order to achieve any of its principal intended purposes.

The effect of the amendments was to enlarge the 1938 definition of "device" to include

- devices intended for use in the diagnosis of conditions other than disease, such as pregnancy;
- in vitro diagnostic products; and
- specific products previously regulated as new drugs, including soft contact lenses, bone cements, and sutures.

Medical devices include almost everything health-care professionals use to diagnose and treat illness, improve human functioning, and support and sustain life. More than 1,700 different types of medical devices are available in the United States today. They represent an industry of nearly $14 billion a year.

The Food and Drug Administration (FDA) is authorized to regulate medical devices during all phases of their development, testing, production, distribution, and use. With their rapid proliferation, the major challenge to FDA has been to deal with the tension between promoting the development and availability of new medical technologies and ensuring that marketed devices are safe and effective.

FDA uses two overlapping systems as its principal means of ensuring the safety and effectiveness of medical devices. The first is a system of checks, reviews, and controls that are applied before a device is made available to the public. The second is a monitoring system designed to provide an "early warning" of problems associated with devices after they are in general use. The assumption is that information on problems experienced with a device will find its way back to FDA, so that it can act to reduce safety risks.

Information developed as a result of several recent congressional inquiries and other analyses have raised questions about whether these systems adequately protect the public health and safety. For example, congressional hearings in 1982-83, a study conducted by the Office of Technology Assessment (OTA) in 1983, and our 1983 evaluation have suggested that the information flow from FDA's postmarketing surveillance of devices may not be informing either FDA or the public about the potential danger of some medical devices. In turn, the Congress may lack a valid basis for evaluating the current regulatory system for its ability to protect the public health and safety.

Objectives, Scope, and Methodology

Objectives

On Feburary 26, 1985, the chairman of the Senate Committee on Governmental Affairs asked us to examine and describe the communications network and its flow patterns for problems associated with medical devices that the FDA has reviewed or approved for marketing. After discussions with the committee staff, we posed three objectives and formulated evaluation questions for each of them.

Our first objective was to describe the transmission of information on problems associated with medical devices after release for public use. To meet this objective, we established the following four questions:

1. How much information on problems associated with devices flows from hospitals to manufacturers, FDA, and other related organizations?

2. What are the characteristics of the problems for which information is, and is not, transmitted?

3. To what extent does the information that is transmitted describe the nature, cause, and consequences of the problems?

4. What factors are thought to influence the decision to transmit information about these problems?

We focused on reports from health-care professionals in community hospitals, in order to determine whether there was a difference in the total number of problems hospital professionals recognize and the number of reports they transmit to outside organizations. We also wanted to determine whether there are differences between the types of problems for which information is transmitted and the types for which it is not. We were particularly interested in whether the reported problems are related to potential or actual injury to patients.

Transmitting information to others about a problem with a medical device does not necessarily mean that FDA will be able to evaluate its performance. This ability depends not only on the volume of information but also on its quality. Therefore, we wanted to determine the quality of the data that are transmitted in order to find out their usefulness in the product performance and safety assessment process.

Finally, we wanted to try to ascertain the factors that influence the decision to transmit information. For example, the potential for litigation, the ease of reporting, and hospital policy might all be expected to play a role in this decision.

Our second objective, which assumed that information of sufficient quantity and quality does actually reach the persons who can respond to problems associated with the use of medical devices, was to describe the actions that FDA and others have taken. The four questions we established were

1. What is the range of responses available to hospitals, manufacturers, FDA, and other related organizations?

2. What is the relative distribution of the types of responses they make?

3. What are the characteristics of the responses to the different types of problems associated with devices?

4. What factors are thought to influence the decision to respond to these problems?

After understanding how information flows, our next logical step was to determine what is done with it. We focused on the different types of responses to a variety of problems, how the responses are made, and how frequently they are made. We wanted to determine whether the characteristics of an event such as an injury or a potential injury are associated with specific types of responses, and we wanted to identify the nature of the transmission—for example, whether information is formally documented and whether it is direct or sent through intermediaries. Finally, we decided to ask the officials of specific organizations what factors influence how they respond to the reports they receive.

Our third objective was to examine the postmarketing surveillance of other goods and services. We established the following two questions:

1. How do federal agencies with similar responsibilities for monitoring hazardous technologies collect information?

2. What other methods and specific practices might FDA use to improve data quality and usefulness?

Our preliminary interviews and literature reviews indicated that many federal agencies have hazard-monitoring responsibilities and operate several types of postmarketing surveillance systems. For example, the Nuclear Regulatory Commission monitors the safety of the operation of nuclear power plants, the Federal Aviation Administration monitors safety in air travel, and the Consumer Product Safety Commission monitors the safety of a wide range of goods and services.

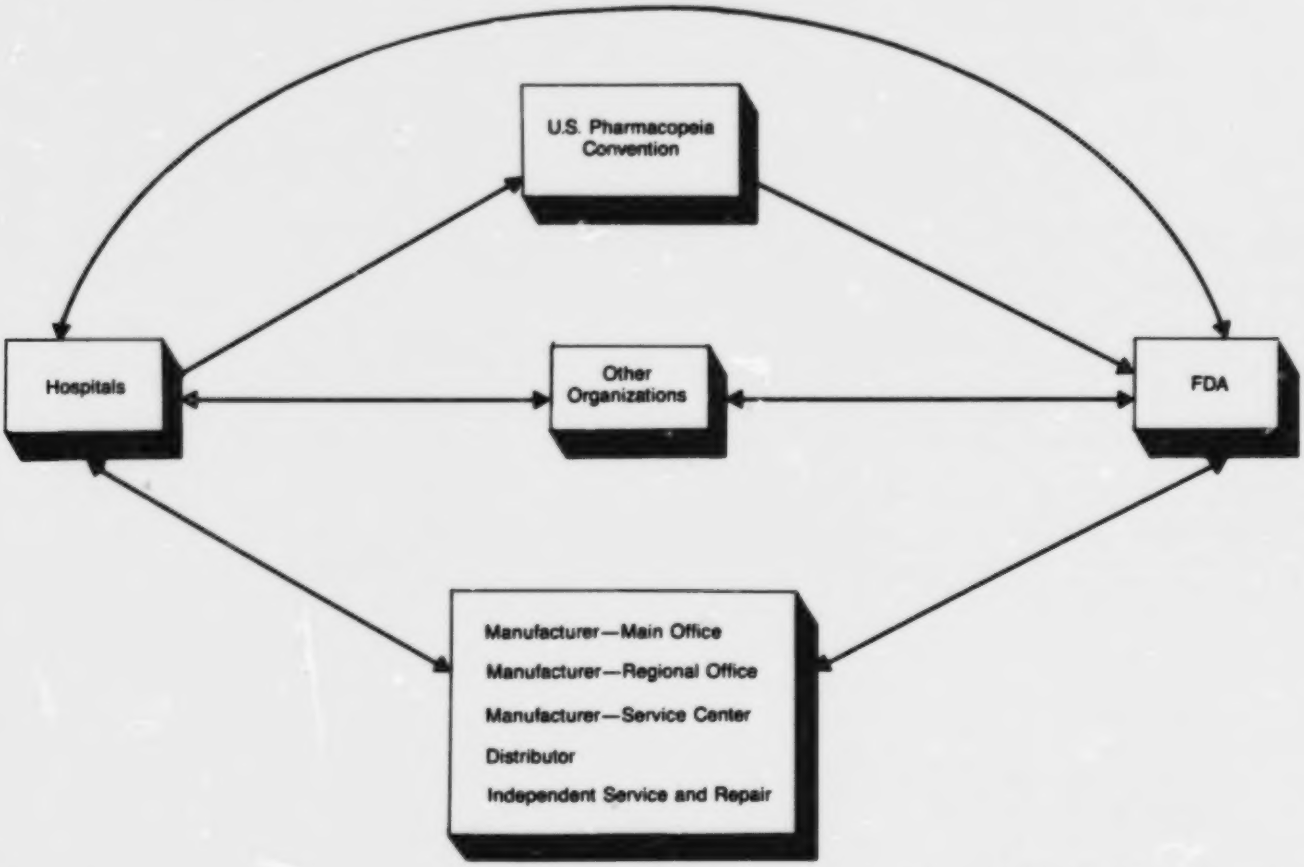
Although the way in which agencies monitor safety differs, all surveillance systems should address generic concerns about adverse events. Among them are the reporting, transmission, quality, and usefulness of data. We wanted to review other federal agencies to determine how they obtain information about problems associated with the use of the technologies they regulate. We hoped to identify alternative methods and specific practices that might apply to the postmarketing surveillance of medical devices. These three sets of questions, our study findings, and our conclusions constitute the primary sections of this report and are reported in chapters 3 through 6.

Scope

Our fieldwork was conducted from March 1985 through January 1986. We carried out an extensive review of the literature and surveyed a nationally representative sample of community hospitals, selected manufacturers of medical devices, FDA, selected federal agencies responsible for monitoring hazardous technologies, and experts in the field.

We analyzed the experiences of a national sample of hospitals that use 1 of 10 selected devices, in order to describe how information about the most significant problems associated with them has flowed through the expected communications network (see figure 1.1). The use of devices outside the hospitals was beyond our scope. We made contact with the manufacturers and other organizations hospitals identified as recipients of information, in order to determine what information they had received and how they responded to it. We developed our inventory of other federal agencies with information-based systems for monitoring the use of a technology and reviewed their systems, in the hope of identifying practices that might be useful for monitoring medical devices. Finally, we interviewed the program managers and staff members in the program offices for the selected systems.

Figure 1.1: A Model of the Expected Communications Network for Medical-Device Problems


U.S. Pharmacopeia Convention
Hospitals
Other Organizations
FDA
Manufacturer—Main Office
Manufacturer—Regional Office
Manufacturer—Service Center
Distributor
Independent Service and Repair

[a] Each element in this model (hospitals, manufacturers, distributors, the Food and Drug Administration, and other organizations) may act as a sender or receiver of messages through the communications channels indicated by the connecting arrows.

Methodology

Our various objectives required different kinds of information from many sources. To fully appreciate the importance of the flow of information about problems related to medical devices in their postmarketing stages, it was necessary to understand what happens to a device and its vulnerability before FDA reviews or approves it for marketing. Therefore, we developed a general operational model of the testing and evaluation process and obtained a flowchart of the ways by which a device may reach the market. We used these as the basis for structured interviews that we conducted with FDA officials about premarketing, after we reviewed evidence of the policies and activities of FDA and other agencies, in order to ensure the consistency of our information.

We narrowed our final sample to 10 devices for tracing information and response patterns between health-care professionals in hospitals and organizations outside them from a larger number nominated by a panel of experts on medical devices. (A detailed description of our criteria and selection process is in appendix V.) We used questionnaires to gather data to confirm the operation of the communications network. After we surveyed the hospitals and examined their reports of problems, we used a confirmation form to verify that the organizations the reports were sent to received them.

We reviewed written documents on the practices of other federal agencies and their program operations, rules, regulations, data collection methods, outputs, and feasibility and evaluation studies, in order to determine the extent to which they address the problems we found in FDA's postmarketing surveillance. We conducted structured interviews with program managers and staff to clarify, confirm, and supplement this evidence.

The nature of the data we collected required both qualitative and quantitative analysis. We systematically reviewed the documents describing FDA's market review and approval and the procedures of other monitoring systems, and we conducted structured interviews with agency officials to clarify, confirm, and supplement what we found. Our statistical procedures for the analysis of the survey data used the statistical package for the social sciences (SPSS-X). We edited, coded, keypunched, and verified the data we collected. We used frequency counts of the relevant variables, crosstabulations of variables that respond to the evaluation questions, and crosstabulations that include variables that might logically specify an established relationship.

The Strengths and Limitations of This Study

The strengths and limitations of this study should be considered in interpreting our findings. One limitation is that the accuracy and completeness of survey data depended largely on the respondents. Whenever it was practical, we confirmed information and resolved inconsistencies by referring to official program documents and consulting experts. In some instances, however, the operating structure of organizations responding to the survey or the nature of the device-associated problem made it impractical to obtain some information.

A second limitation derives from the evaluation questions. Our purpose was not to determine the scope or frequency of device-associated problems. That type of study would require data indicating the number of device-associated problems in comparison to the number of applications of specific devices. Instead, our focus was on the viability of the surveillance system for marketed medical devices. That is, If a problem occurs, who knows about it and reports it? What route does the information travel? What are the responses to the event? We also did not study "problem devices." We selected specific devices in use today for which a panel of experts on medical devices indicated that we should be able to trace an information flow.

A third limitation derives from our review of alternative systems. It was not our purpose to advocate the adoption of particular monitoring systems. Since we do not have independent evaluations of their relative effectiveness, we did not judge the superiority of one system over another. Instead, we examined monitoring systems that are managed by federal agencies with responsibilities similar to FDA's and that operate under similar constraints, and we looked for techniques and strategies that might be transferable to medical devices.

Our study has noteworthy strengths as well. First, our survey covered a national sample of hospitals representing more than 76 percent of the general-care community hospitals in the United States. The 81-percent response rate provided a strong basis for our findings. We are assuming that the relatively full response rates for both the screening questionnaire and the follow-up survey were randomly distributed. We believe that if those that did not respond had responded, our findings would be the same. We received questionnaires from hospitals of all bedsize categories and from all regions of the country.

Second, our interview respondents had a comprehensive range of interests and experiences relevant to this topic. Among them were program managers, staff members in program offices, experts from universities, physicians involved in private-sector research, representatives from professional associations, device manufacturers, and consumer-interest groups. The panels that helped us select our sample of devices, review our design development, and develop this report reflected the same diversity of background.

Third, this report provides new and important information on the structure and operation of the information network for medical devices. We know of no previous studies that systematically describe the network and its operation and also indicate the circumstances in which information is and is not transmitted. The scope of our study allows us to suggest where interventions would have the greatest effect.

Finally, the design of this study provides a baseline for evaluating several recent initiatives in postmarketing surveillance, such as the medical-device reporting rule. To our knowledge, no set of data existed for conducting before-and-after evaluation research before our study.

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Chapter 2

Premarketing Review and Approval and Postmarketing Surveillance: Potential Vulnerabilities

Recent decades have seen massive changes in the variety and complexity of medical devices; greater dependence on technology for most aspects of medical diagnosis, therapy, and care of the ill; and a phenomenal rise in automation. Radical treatments now involve plastic, metallic, and electronic implants. Vast knowledge and technical responsibility are demanded of each member of the health-care team. Health professionals must now choose between many medical devices, some of which lack product standardization, become rapidly obsolete, or malfunction in ways that defy detection until patients have been injured.

FDA reviews and approves devices for sale and monitors their performance after marketing through its Center for Devices and Radiological Health and the authority granted it under the 1938 Food, Drug, and Cosmetic Act and its amendments. In this chapter, we discuss three main topics: the 1976 amendments to the Food, Drug, and Cosmetic Act, the premarketing processes in which devices are reviewed and approved for commercial distribution, and FDA's postmarketing surveillance system.

The 1976 Amendments to the Food, Drug, and Cosmetic Act

FDA has been described as the principal consumer-protection agency of the federal government. FDA's authority over the regulation of medical devices has increased as the devices have become more numerous and complex and as the potential threat of unsafe and ineffective products has become greater. The 1976 Medical Device Amendments authorized FDA to regulate medical devices during all phases of their development, testing, production, distribution, and use. Among other things, the amendments

- require businesses involved with medical devices to register their establishments annually and list their devices;
- require FDA to classify and regulate devices by degree of risk according to three classes I, II, and III;
- authorize FDA to reclassify devices on the basis of new information, including that which may be developed after a device has been approved for marketing;
- require premarketing notification for all new devices and premarketing approval or reclassification of "new" devices found to be not substantially equivalent to devices in use before the amendments;
- provide for the protection of patients against experimental devices;
- authorize FDA to ban dangerous, defective devices from use; to require manufacturers to repair, replace, or make refunds for defective or hazardous devices; to require that consumers and health-care professionals

be provided with adequate information to help eliminate unreasonable risk; and to restrict the use of specific devices.

The Classification of Devices According to Potential Risk

The centerpiece of the 1976 amendments was the classification of three degrees of potential risk. Each device must be classified according to what is needed to reasonably ensure its safety and effectiveness. Medical devices that were marketed before the amendments were assigned to one of the three classes by medical specialty panels.

Class I devices are subject to minimum regulation. General controls such as registration, listing, premarketing notification, regulations for good manufacturing practices, and prohibitions against adulteration and misbranding are sufficient to provide a reasonable assurance of safety and effectiveness. These devices are not used in supporting or sustaining life, are not important in preventing the impairment of human health, and do not present a potentially unreasonable risk of illness or injury. They include tongue depressors, elastic bandages, ice bags, bed pans, and skill-pressure protectors. The regulations for good manufacturing practices are applied to their manufacturing, packaging, storage, and installation.

Class II devices include syringes, bone plates, hearing aids, resuscitators, and electrocardiograph electrodes. General controls are insufficient to provide reasonable assurances of their safety and effectiveness, but scientific information is sufficient to establish performance standards that will provide such assurances.[1] FDA is required to develop and establish performance standards that can specify their materials, construction, components, ingredients, and labeling.

Class III devices are the most rigidly controlled. They are potentially very hazardous and usually require approval before marketing. General controls are insufficient to provide reasonable assurances of their safety and effectiveness, and sufficient information does not exist to establish performance standards to provide such assurances. These devices are life-supporting or life-sustaining, substantially important in preventing the impairment of human health, or present a potentially unreasonable risk of illness or injury.

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[1] By early 1984, final and proposed regulations had classified or proposed to classify nearly 1,100 of more than 1,700 devices in class II, but FDA has issued no mandatory performance standards for class II devices.

The concept of the regulation of devices in accordance with their potential risk has a direct effect on the ways in which a device can be approved for commercial distribution. A class I device is subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act of 1938, as amended. A class II device must comply with the general controls and applicable performance standards. A new or transitional class III device may be released for commercial distribution only after obtaining premarketing approval or being reclassified.[2]

Devices in all three classes found to be "substantially equivalent" to products on the market before 1976 have been put in the same class with their preamendments counterparts and can be immediately released for commercial distribution. A postamendments device, one first marketed on or after the effective date of the amendments, is automatically placed in class III and must have premarketing approval or be reclassified, unless FDA finds that it is substantially equivalent to a preamendments device that may be commercially distributed without premarketing approval or reclassification. The manufacturer may petition FDA to reclassify it from class III into I or II.

In order to develop the information on safety and effectiveness that is necessary for the approval of a class III device, the sponsor of the device must apply to FDA for an "investigational device exemption." After receiving the exemption and conducting the requisite investigations, the sponsor may submit a premarketing approval application that presents the results of its investigations. If FDA approves this application, the device may be marketed. The alternative product development protocol route, in which FDA takes an active role with the manufacturer in developing premarketing data, has rarely been used. Transitional devices are automatically placed in class III, which means they must be approved before marketing, but they may be reclassified upon petition.

The Role of the Center for Devices and Radiological Health

FDA formed the Center for Devices and Radiological Health in 1982 to centralize the implementation of the 1976 amendments and the development of programs intended to ensure that unsafe and ineffective medical devices are not sold in the United States. The center has nine offices: management and systems, training and assistance, device evaluation, science and technology, compliance, health affairs, health physics, standards and regulations, and the office of the director.

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[2] Transitional devices were regulated by FDA before 1976 as drugs and are included in the 1976 amendments under the expanded definition of medical devices.

The decision to approve devices for marketing and their subsequent monitoring is primarily the responsibility of the offices of compliance and device evaluation. The latter is responsible for scrutinizing manufacturers' claims and test results; reviewing premarketing notifications, premarketing approval applications, reclassification petitions, and applications for investigational device exemptions; and monitoring clinical trials. The office of compliance is responsible for monitoring compliance with the Federal Food, Drug, and Cosmetic Act, the other statutes FDA administers, and FDA's regulations; investigating reported problems and recalls; monitoring labels and advertising; and developing a data bank on all devices marketed in the United States.

The Premarketing Review and Approval Process

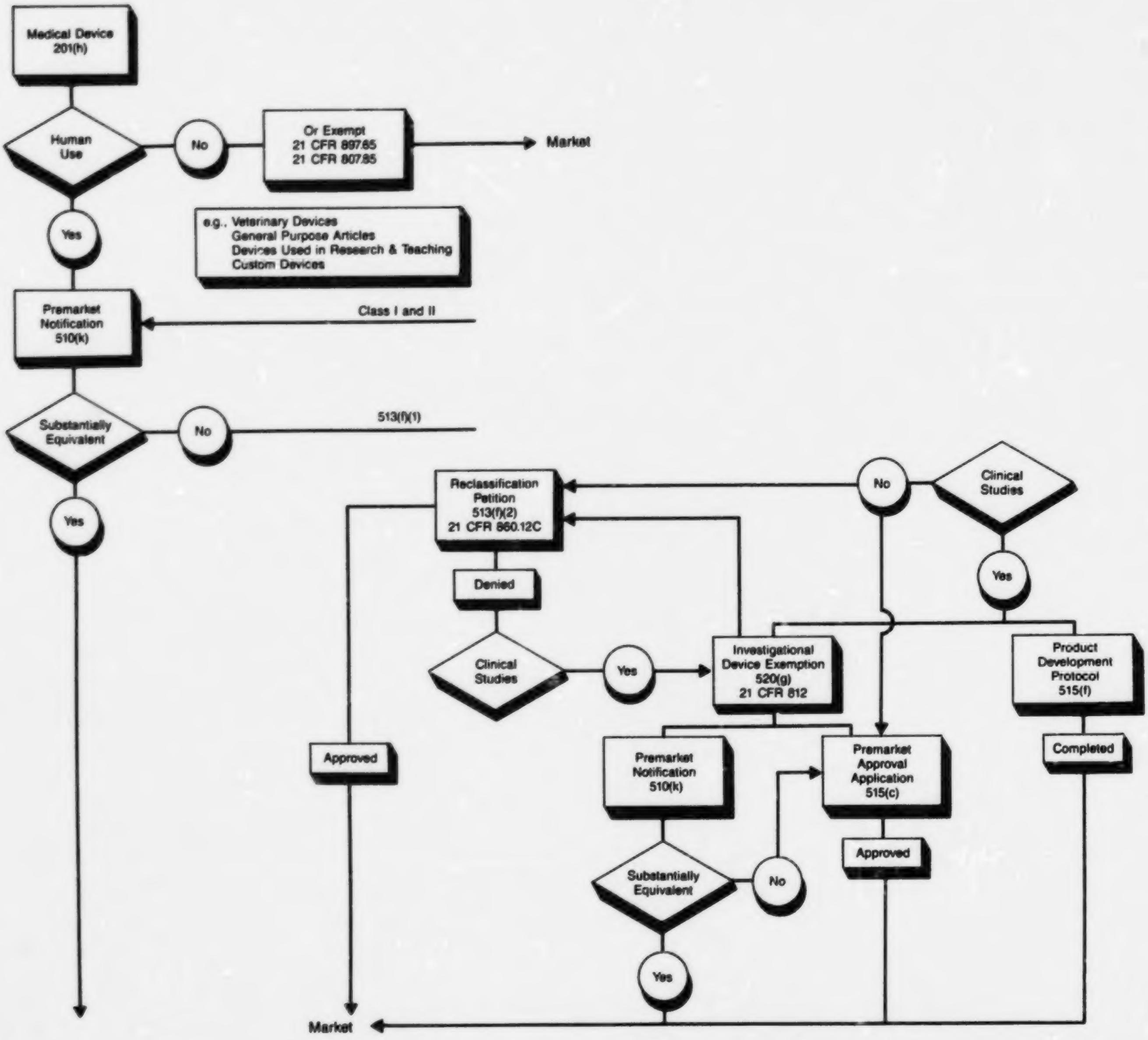
A schematic model developed by FDA illustrates the various routes that a device may travel to commercial distribution. (See figure 2.1 on p. 26.) We discuss the four principal routes below.

Premarketing Notification (510(k))

Since 1976, premarketing notification has been the predominant route to commercial distribution. Section 510(k) of the Food, Drug, and Cosmetic Act as added by the 1976 amendments requires all device manufacturers to notify FDA at least 90 days before they intend to introduce a device into the market either for the first time or so significantly changed or modified in its intended use as to affect its safety and effectiveness. FDA must also review manufacturers' claims that a device is substantially equivalent to some other device marketed before 1976.

The number of premarketing notifications has increased steadily. Since 1976, FDA has processed 32,410 individual notifications, including approximately 5,500 in 1984 (the latest year of available data at the time of our review). The importance of this route to market is clear when shown in contrast to the premarketing approval route: only about 70 applications are made each year, on the average.

Figure 2.1: FDA's Premarketing Review and Approval Process for Medical Devices


Medical Device 201(h)
Human Use
No
Or Exempt 21 CFR 897.85 21 CFR 807.85
Market
Yes
e.g., Veterinary Devices
General Purpose Articles
Devices Used in Research & Teaching
Custom Devices
Premarket Notification 510(k)
Class I and II
Substantially Equivalent
No
513(f)(1)
Yes
Reclassification Petition 513(f)(2) 21 CFR 860.12C
No
Clinical Studies
Yes
Denied
Clinical Studies
Yes
Investigational Device Exemption 520(g) 21 CFR 812
Product Development Protocol 515(f)
Approved
Premarket Notification 510(k)
Premarket Approval Application 515(c)
Completed
Approved
Substantially Equivalent
No
Yes
Market

Source: Department of Health and Human Services, Regulatory Requirements for Medical Devices: A Workshop Manual, FDA 83-4165 (Washington, D.C.: June 1983), p. 1-9.

The contents of 510(k) notifications range from minimal information for review to detailed results of clinical trials. FDA officials indicate that the majority provide minimal information and that additional data are required for one third of all submissions. They indicate also that it takes an average of 60 days to review notifications, although the law allows 90 days. If FDA does not act within 90 days, the device may go to market.

Under section 510(k), a manufacturer must identify how a device is similar to a preamendments device in its intended use, operating principal, design and specifications, energy source, processing procedures, sterilization, and accuracy, precision, specificity, and sensitivity in performance. Significant differences must also be identified and explained. FDA may request more information or find that the device is or is not substantially equivalent.

If FDA finds the device substantially equivalent, it may be commercially distributed. Fewer than 2 percent of the submissions are found to be not substantially equivalent. FDA officials point out that a finding of substantial equivalence does not represent and should not be construed as a statement of a device's safety and effectiveness. It means only that the device is substantially equivalent to a preamendments class I, II, or III device. In general, preamendments class II and III devices have not been required to be safe or effective.

The results of our review and a draft report of an FDA task force indicate that the premarketing notification process is potentially vulnerable because of the subjective criteria manufacturers are allowed for their 510(k) submissions, the vague definition of "substantial equivalence," and problems of staffing resources at FDA. Some changes manufacturers make to devices already on the market require notification, but FDA requires it only of changes that could significantly affect safety or effectiveness. Manufacturers decide whether a proposed modification requires a premarketing notification; a manufacturer who decides that a notification is not required may proceed to market without FDA's knowledge or review. FDA officials told us that in cases like this, they become aware of device changes by inspecting manufacturers' records and receiving reports of adverse experience.

In 1985, FDA did not have written standards or guidelines for 510(k) reviews, and experts at FDA differ in their interpretation of "substantially equivalent." One official told us that all devices approved under 510(k) are substantially equivalent to their preamendments counterparts, and another official stated that some are called "substantially equivalent" even though they have become less and less like the 9-year-old originals. This situation is referred to as "equivalency creep."

In giving examples of this phenomena, a number of experts and the literature we reviewed point to the manner in which several new medical technologies have been regulated. They argue that when the Congress passed the amendments, it envisioned that novel medical devices would be reviewed primarily through the premarketing approval application process in section 515(c). However, faced with its first premarketing review of a bioengineered medical diagnostic device, FDA determined that the 510(k) route would be acceptable, arguing that substantial equivalency should be evaluated in the context of the results of using the device, not the novelty of the assay systems it used to analyze clinical specimens or the technology involved in its manufacture. FDA took the position that the most important factor was whether or not the test results the device produced were essentially the same as results obtained by other preamendments diagnostic methods. In this case, it was less important that the operative mechanisms or the specific assay systems of the two tests differed, as long as the clinical information they provided was the same.

This administrative compromise is sometimes referred to as a "hybrid 510(k)" or "mini-PMAA." The procedure seems to allow FDA a shortcut to ensure diagnostic effectiveness. A notification under 510(k) can be reviewed without the involvement of an advisory panel and the general counsel review that are required for applications under 515(c), although the agency can consult them if it needs help. The legislative history of section 510(k) does to some extent support the agency's discretion in allowing a bioengineered product to proceed along the notification route, if there is no question about safety and effectiveness. We do not know the extent to which it has been used or whether its use for novel bioengineered products has gone beyond what the Congress envisioned in 1976.[3] We plan to explore this issue in a future study.

FDA has found some devices substantially equivalent to preamendments devices that lacked the latest technological or safety features of the newer models. The safety and effectiveness of neither the original devices nor their later versions had been established. In some cases, devices some experts call "new-new" have also been found substantially equivalent.

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[3] Approximately 55 bioengineered devices have been approved following 510(k) notifications since the first was cleared in 1981.

At the time of our study, FDA had not yet issued standards for class II medical devices; it has required manufacturers to submit proof of the safety and effectiveness of only three class III devices marketed before 1976. Therefore, some medical devices that experts believe belong in class II or class III are regulated and reach the market in much the same way as the relatively innocuous tongue depressor.

The ability of FDA staff to make informed judgments about the substantial equivalence of devices and, therefore, about whether they can go directly to market may be weakened still further by an annual staff turnover rate of 15-20 percent at the center. Thus, many evaluators who learn and develop skills from on-the-job training are not provided an adequate opportunity to learn from long-term staff members but must learn on their own and under rather severe time constraints.

In addition, we learned from FDA officials that the recruitment of qualified personnel is often difficult. For example, they told us that FDA is not competitive with private industry in its hiring and compensation capabilities. Evaluators who make the decisions about substantial equivalence must do so with relatively little experience, without written guidelines, and in the face of inconsistent review procedures within and between FDA divisions.

There may be staffing problems at higher levels as well. At the time of our review, the director and one branch chief in one of the device divisions were "acting" and the two remaining branch chief positions were vacant.

Premarketing Approval Application (515(c))

All class III devices must have premarketing approval in accordance with section 515 of the 1938 Federal Food, Drug, and Cosmetic Act, added by the 1976 amendments. This includes preamendments class III devices, postamendments class III devices that are substantially equivalent to class III devices marketed before the amendments, postamendments devices that are not substantially equivalent to preamendments devices, and transitional devices.

FDA's review of premarketing approval applications has three major steps: (1) administrative review to determine whether an application includes all the required information and is otherwise suitable for filing, (2) scientific and regulatory review by scientific and compliance personnel, and (3) review and recommendation by an advisory committee mandated by section 515(c) and composed of experts from the medical and other academic fields, in accordance with section 513(g).

The administrative review is the "gatekeeper" that assures FDA of having a complete application before the device is put through the scientific and regulatory review. For this latter step, the amendments and FDA's regulations set forth standards of scientific evidence that the agency must apply. The evidence may be based on controlled studies and investigations, objective trials without matched controls, documented case histories conducted by qualified experts, reports of significant experience (such as the results of research conducted in foreign countries), or any combination of these.

For the devices that have been approved for marketing through this route and are later changed or made to deviate from the conditions described in the original approval, manufacturers must obtain FDA's approval of a supplemental premarketing application describing the changes and showing that the changed device remains safe and effective. Supplements are required for, among other things, adding a new indication for use, using a new principal of operation, and adding a color additive that comes in contact with the body for a significant period of time.

Each year, many modified medical devices and new devices not substantially equivalent to others marketed before the 1976 amendments are introduced into the marketplace. They include complex drug-delivery systems, life-supporting prostheses, and sophisticated electronic devices for controlling, modifying, and performing essential physiological functions. FDA requires premarketing approval to ensure that products whose use is associated with the highest risk have a reasonable probability of being safe and effective.

The 1985 draft report from FDA's premarketing approval application task force found that most criticisms of the process could be grouped into two categories: the length of review and the scientific quality of the review. All the criticisms concerning the length of review were summarized in one: reviews take too long, in most cases exceeding the statutory limit of 180 days. Criticisms of the scientific quality of the review included

- too few staff physicians to evaluate industry assertions,
- too many class III devices allowed to go to market through section 510(k),

- inconsistent data requirements for deciding safety and effectiveness,
- lack of guidelines describing the data required for approval of devices in various generic groups,
- inconsistent labeling requirements for different devices within a given category,
- overreliance on the recommendations of advisory panels, and
- inadequate documentation of advisory panel recommendations and approval decisions.

Trying to determine the causes of each criticism and to consider possible solutions, the task force analyzed the accumulated information and reported several findings with suggestions for streamlining and expediting the process. The report indicated that the Center for Devices and Radiological Health has taken steps to correct some of the problems and is considering others. Some of the recommendations would require statutory changes in the amendments.

Reclassification

The 1976 amendments allow FDA to reclassify devices into a less stringent category—from class III to class II or I, for example. Our review and an FDA task force study of the reclassification procedures indicated that the statute is procedurally so specific that it does not allow for flexibility or change in the light of agency experience.

Reclassification is addressed in five different provisions of the amendments, allowing for the reclassification of (1) postamendments devices that are not substantially equivalent to devices marketed before the amendments and other devices that have been reclassified, or so-called "new-new" devices (section 513(f)), (2) devices that on the date the amendments were enacted were regulated as new drugs (section 520(1)), (3) class II devices for which FDA has initiated a proceeding to establish a performance standard (section 514(b)), (4) class III devices marketed before 1976 for which FDA has issued a proposal to require premarketing approval (section 515(b)), and (5) previously classified devices with new information (section 513(e)).

Under each of these provisions, specific procedures are laid out, but they vary considerably. For example, panel review is sometimes mandatory and other times discretionary. Reclassification must be by regulation sometimes, and other times it must be by order. Sometimes the review period is 180 days and sometimes it is 210 days. The lack of uniformity in the review and uncertainty about necessary rigor raise concern that the generally complex statute does not promote either safety or effectiveness.

The nondisclosable information on safety and effectiveness contained in premarketing approval applications cannot be used to support reclassification decisions, even when it is relevant. Therefore, it is to a manufacturer's advantage to seek premarketing approval rather than reclassification. A manufacturer whose device is approved gains a competitive edge in the market. However, when a device is reclassified, all devices in its generic category are also reclassified. Therefore, relatively few manufacturers have sought reclassification.[4] According to an FDA study, this process has contributed to delays in obtaining marketing approval for some devices and has inhibited competition.

Product Development Protocol

The product development protocol provides an alternative route for gaining marketing approval for class III devices. The investigation of a device and the development of information necessary for a decision on marketing approval are merged into one regulatory mechanism. The major difference between the protocol route and the premarketing notification and approval routes is that in the protocol, FDA formally participates in deciding on the testing protocol to be used with a device. Manufacturers may choose any of these routes, but they have not chosen the product development protocol since 1982 because (1) the sponsor of a device can obtain testing advice from FDA's scientific reviewing divisions informally, without FDA's formal and continuous participation in the testing process, and (2) the other routes are less labor-intensive and require fewer resource expenditures for FDA.

Postmarketing Surveillance

A greater awareness of the possibility of serious adversity associated with new technologies has resulted in giving greater importance to early detection and reporting. Postmarketing surveillance is the collection and evaluation of information on adverse events associated with currently marketed devices, in order to ensure the public safety and to support the development and updating of standards, the reclassification of devices, and regulatory decisionmaking. It seeks information about serious problems and smaller incidents that may seem insignificant individually but point to a potentially serious problem when considered in a broader frame of reference.

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[4] Thirty-nine reclassification petitions have been filed since 1976; 33 of them have been approved.

Good Manufacturing Practices

Prior to December 1984, FDA relied on two principal sources for surveillance data: good manufacturing practices inspections and the device experience network. Section 520(f) of the Food, Drug, and Cosmetic Act, added by 1976 amendments, authorizes FDA to promulgate regulations that specify practices in the manufacture, packaging, storage, and installation of devices. The regulations FDA promulgated in July 1978 serve as a framework within which manufacturers develop individual quality-assurance programs. Good manufacturing practices include controls over manufacturing, specifications, processing procedures, device components, packaging, labeling, manufacturing equipment, and records.

Information on good manufacturing practices is used primarily for compliance purposes. FDA inspects manufacturing facilities and operations every 2 years. FDA also inspects manufacturers' records, particularly complaint and service files. A complaint is a written or oral expression of dissatisfaction regarding the identity, quality, durability, reliability, safety, effectiveness, or performance of a device. Complaints received by telephone must be recorded and reviewed for possible investigation by a formally designated unit within the firm. If a device, or any of its components, fails to meet specifications after its release for distribution, it must be investigated and a written record must be kept of the investigation and resultant action. A complaint involving a hazard to safety, an injury, or death must be immediately reviewed, evaluated, and investigated. Complaints involving hazard, injury, or death must be filed separately. When the site of the formally designated complaint unit is different from the manufacturing site, duplicate complaint investigation reports must be maintained at the two sites.

The primary vulnerability associated with using good manufacturing practices inspections for postmarketing surveillance is that the criteria for determining what is included in the complaint file are flexible and reviewing such files is labor-intensive. Not all correspondence with customers has to be included in the complaint file. Repairs characterized as "routine service" are excluded, and manufacturers define routine service. The maintenance of records of repair is not specifically required but is recommended as input for determining the reliability of quality-assurance programs.

In 1982, FDA surveyed the manufacturers' records required under the good manufacturing practices regulations. Sample-based projections for the number of reports manufacturers received in 1 year ranged from 2 to 147 deaths and from 441 to 1,431 serious injuries. It was also estimated that 168,000 product deficiencies would be reported and that FDA inspectors would be required to review about 995,000 complaint and service maintenance file records each year, in order to collect the information necessary for the adequate postmarketing surveillance of medical devices. The study concluded that reviewing complaint files was not a timely or efficient way for FDA to become aware of serious problems and that another strategy for obtaining information from manufacturers was needed.

FDA's Problem-Reporting Program and Device Experience Network

FDA's problem-reporting program is a voluntary, spontaneous reporting system operated by the U.S. Pharmacopeia Convention, which forwards reports it receives, primarily from health-care professionals through their professional associations, and from hospitals (with identifiers removed upon request) to FDA, where they become part of the device experience network. The network is a centralized, automated data processing system for the collection, processing, and evaluation of device-associated problem reports. It includes reports from the problem-reporting program, good manufacturing practices inspections, government quality-assurance programs (such as those for devices used in the Veterans Administration and Department of Defense hospitals), and the national electronic injury surveillance system as well as radiological testing reports and staff-generated reports based on articles, conferences, and other sources. The problem-reporting program accounts for approximately 60 percent of all the reports in the network. FDA receives approximately 3,300 reports annually, of which approximately 2,000 are from the program.

Reviewing and evaluating the program and network were beyond our scope, although a 1983 GAO review and congressional testimony by FDA officials indicate that the program and network suffer from serious problems, especially underreporting and use of the data for little other than compliance purposes. FDA has argued that few users of devices report to the program because of the current atmosphere of medical malpractice litigation, which makes it very difficult to establish or expect a voluntary flow of device-related information from the health-care community. FDA believes that manufacturers probably receive more reports concerning serious injuries and deaths than it does because health-care practitioners, who are cautious about reporting these events to anyone, tend to report to manufacturers in order to determine the cause of an event and prevent its recurrence.

Underreporting means that the program and network simply do not function as an early warning system. If FDA does not receive notifications, it cannot identify immediate or potential health hazards or prevent multiple injuries associated with the use of medical devices. Underreporting also means that FDA cannot accurately estimate the number of problems and, thus, cannot assess their extent or trends or plan the disposition of its resources to solve them. Finally, underreporting means that FDA may not be informed of a sufficient number of relatively rare but significant events to assess patterns of hazard or their causes.

FDA officials responsible for the problem-reporting program are well aware of the underreporting and some of the contributing factors. They have initiated several solutions. To publicize its system, FDA mails descriptive materials directly to 10 departments in 6,500 hospitals annually. FDA has experimented with the form and contents of its mailings. The current package consists of a folder with the USPC logo, 10 pages of promotional material, and 10 reporting forms. The forms are postage-paid and self-mailing, photocopying them does not prevent mailing them under the postage frank printed on them, and they carry a toll-free telephone number that has been in operation since 1979.

FDA also publicizes its efforts through paid advertising in technical journals and two monthly FDA publications. Edited reports in the Device Bulletin attempt to show the importance of reporting. The Panel Reports contains unedited reports categorized by each of the 19 device panels, such as anesthesiology and cardiology. However, the circulation of these publications is limited to persons who have previously reported to FDA.

In 1984, FDA established contracts with health departments in seven states to conduct experimental promotional efforts and to gather feedback from health-care professionals on FDA's efforts to increase reporting. The promotional efforts consisted of presentations to a minimum of 50 hospitals in each of the seven states. Five of the seven health departments have submitted final reports on their efforts; all five indicated a generally low level of program awareness. Their recommendations included an increase in promotional efforts.

Despite these initiatives, the number of reports hospitals make to FDA's system remains negligible.

The Medical-Device Reporting Rule

In light of its findings from its 1982 survey of manufacturers' records under the good manufacturing practices regulations and the problems in the device experience network, FDA promulgated a mandatory medical-device reporting rule that went into effect on December 13, 1984. The central element of the rule is that manufacturers and importers are required to report to FDA when they receive or otherwise become aware of information that reasonably suggests that one of their marketed devices has caused or contributed to serious injury or death or has malfunctioned and is likely to cause or contribute to serious injury or death if the malfunction recurs. FDA concurred with comments it received before the final regulation was issued that independent distributors should not be required to report because "in all likelihood, a manufacturer or importer whose identity is known will be informed by device users and independent distributors of reportable events." Thus, the most serious vulnerability of the rule is its scope. The current rule does not require independent distributors of medical devices or hospitals to report incidents to manufacturers or FDA. It is not the intent of the rule to address the communication links between hospitals and manufacturers, hospitals and independent distributors, hospitals and FDA, and independent distributors and manufacturers.

Summary

Our review suggests that FDA is obliged to make trade-offs between the "push" of its mandate to make the latest medical-device technologies available to the public quickly and the "pull" to ensure their safety and effectiveness. We have identified the potential vulnerability of four principal routes to the commercial distribution of medical devices and three elements of the postmarketing surveillance system employed to monitor them once they are in general use.

In the premarketing review and approval of devices,

1. premarketing notifications under section 510(k) of the Food, Drug, and Cosmetic Act, as added by Medical Device Amendments of 1976, do not gather adequate testing information from manufacturers, allow for subjective criteria, contain a vague definition of "substantial equivalence," and are inadequately reviewed because of a high degree of evaluator staff turnover and difficulty in recruiting qualified personnel at the Center for Devices and Radiological Health;

2. premarketing approval applications under section 515(c) require an overly lengthy review (most cases exceed the statutory limit of 180 days), which may cause manufacturers to use the more vulnerable

premarketing notification process, and the scientific quality of the review is questionable;

3. reclassification generally lacks uniformity and the necessary rigor in its review procedures (for example, the review period varies and panel review can be either mandatory or discretionary); and

4. product development protocols have no known vulnerability but are not generally used.

In the postmarketing surveillance system,

1. good manufacturing practices records inspections are labor-intensive and inefficient and use subjective criteria to differentiate between complaints and repair and service reports;

2. the problem-reporting program and device experience network underreport adverse events and their data have limited usefulness; and

3. the medical-device reporting rule has a limited scope of applicability, because it does not include independent distributors or hospitals.

FDA has not established performance standards for class II devices. It requires manufacturers to submit proof of the safety and effectiveness of only three class III devices marketed before 1976. Therefore, some medical devices that belong in class II or III are regulated and reach the market much in the same way as devices that pose no unreasonable risks.

It is clear that premarketing review and approval will never be perfect. Suggestions and recommendations have been made by FDA task forces and others to address many of their specific and inherent problems. It seems, however, that even if all the recognized problems were solved, it would still be necessary to achieve a certain balance between timeliness and safety and effectiveness. The premarketing checks, reviews, and approvals are necessary but not sufficient. Therefore, postmarketing surveillance must work in concert with the premarketing review and approval processes in order to provide the quantity and quality of information that could serve as an early warning for device problems once they are released for commercial distribution.

Information Transmission Patterns for Problems Associated With Medical Devices

How We Approached Our First Objective

Premarketing notification and approval help ensure that medical devices on the market are safe and effective, but even when these preventive measures work admirably, they cannot identify all the problems that may be associated with a device in general use for an extended period of time. We looked at circumstances before the medical-device reporting rule went into effect in December 1984 in order to learn what information was then being transmitted and the actions that were being taken to remedy the problems. We wanted to develop baseline data for a comparison test of the communications network after the rule.

In the model of the postmarketing communications network we presented in chapter 1 (see figure 1.1), information can be sent by hospitals directly to one or more of the following organizations: (1) FDA through USPC and the device experience network, (2) the manufacturer or independent distributor of the device, and (3) a third-party monitoring organization. Information sent to the manufacturer or distributor or the third party may be redirected to FDA. Our first objective was to describe this flow of information about problems associated with devices after they have been released for public use. We established the four questions listed in chapter 1:

1. How much information on problems associated with devices flows from hospitals to device manufacturers, FDA, and other organizations?

2. What are the characteristics of the problems for which information is, and is not, transmitted?

3. To what extent does the information describe the nature, cause, and consequences of the problems?

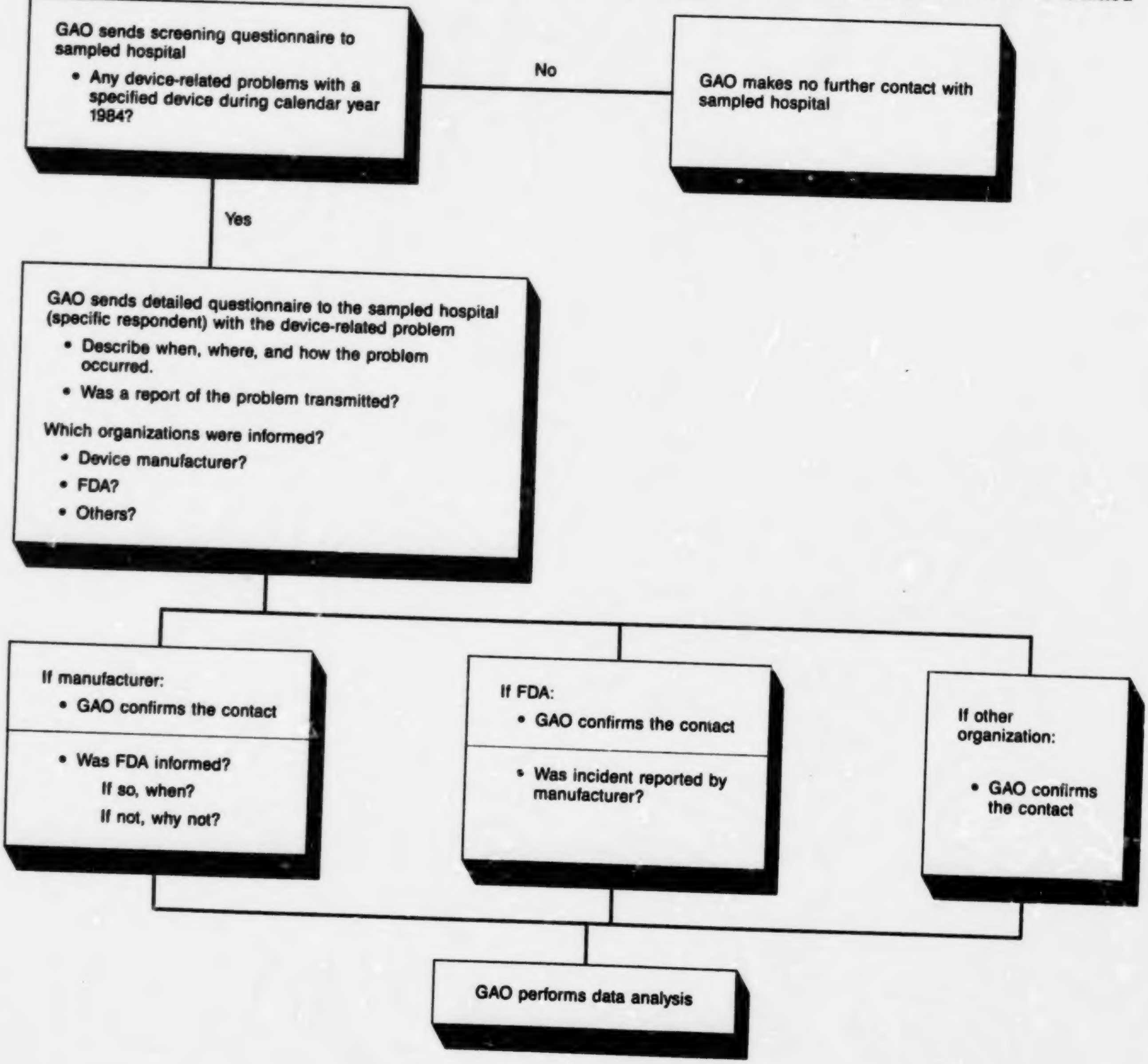
4. What factors are thought to influence the decision to transmit information about these problems?

The four main sections of this chapter give the details of what we found.

To gather our data, we mailed our screening questionnaire on our sample of 10 medical devices to 10 stratified random samples of hospitals (200 hospitals per strata), 1 device for each hospital. We asked 5 individual respondents from each hospital if they had experienced any problem during 1984 with the use of a specified device. Eighty-one percent (1,651) of the 2,038 hospitals that received the package of screening questionnaires returned at least 1 questionnaire. In many cases, we received several screening questionnaires identifying the same problem from a single hospital. In these cases, we received more than one completed, full hospital questionnaire identifying a single problem from persons occupying different positions within the hospital. In order to avoid duplication, we selected the "most fully complete" questionnaires for our analysis of the full hospital questionnaire. (Appendix V contains details of our sampling procedures.)

Respondents in the affirmative were asked to give the date (actual or estimated) of the most significant safety problem. We used the results of this screening survey to identify specific individuals, to whom we sent a more detailed questionnaire; the response rate for this questionnaire was 78 percent. This means that at least 78 percent of the individuals who had identified a problem on the screening survey and subsequently received the detailed questionnaire returned the more detailed questionnaire. This procedure is illustrated in figure 3.1. All results are subject to sampling and nonsampling error. The numbers and percentages in this report should be considered estimates relating to the number of incidents involving the 10 devices.

Figure 3.1: Our Methodology for Finding Out How Information on Problems Associated With Medical Devices Is Transmitted


GAO sends screening questionnaire to sampled hospital
• Any device-related problems with a specified device during calendar year 1984?
No
GAO makes no further contact with sampled hospital
Yes
GAO sends detailed questionnaire to the sampled hospital (specific respondent) with the device-related problem
• Describe when, where, and how the problem occurred.
• Was a report of the problem transmitted?
Which organizations were informed?
• Device manufacturer?
• FDA?
• Others?
If manufacturer:
• GAO confirms the contact
• Was FDA informed?
If so, when?
If not, why not?
If FDA:
• GAO confirms the contact
• Was incident reported by manufacturer?
If other organization:
• GAO confirms the contact
GAO performs data analysis

The Level of Information Transmission

From the full hospital questionnaires, we obtained data on 1,175 individual problems associated with medical devices.[1] Seventy percent of the hospitals that identified problems with a device identified a single problem; 30 percent identified 2 or more separate problems. Problems were reported for all 10 medical devices included in our study, representing more than 85 different manufacturers.

We found that of the 1,175 device-related problems identified in our survey, 593, or only about 51 percent, were made known to any organization outside the hospital in which they occurred. Of these 593 problems, 543, or about 92 percent, were reported to the manufacturer or independent distributor of the device.[2] Approximately 8 percent were transmitted to "other organizations," such as the Emergency Care Research Institute. Less than 1 percent of the problems were reported directly to FDA or the device experience network. It is evident that our expected model of information flow does not correspond to the reality of the diffuse communication about medical devices.

With regard to message quality, the vast majority of all the reports, 83 percent, transmitted from the hospitals were oral. Written reports were made on only 10 percent of the problems, and a combination of written and oral reports accounted for 7 percent.

Although our hospital respondents indicated that manufacturers were the principal target of their external reports, a closer analysis of the data indicates that the information flow is not this direct. There may be one or more intermediaries between a hospital and a manufacturer's headquarters, where a blockage or breakdown in the flow of information can and does occur (see figure 3.2). Manufacturers noted variations in the nature and quality of the information they received from these intermediaries. For example, there is no contact between manufacturers and users for devices sold outright to dealers or rental agencies. When company sales or service representatives satisfactorily resolve a problem, no record of it may be kept. However, repair and service work performed under warranty often requires the approval of the manufacturer's main office for payment, and in these cases a record of problems is established.

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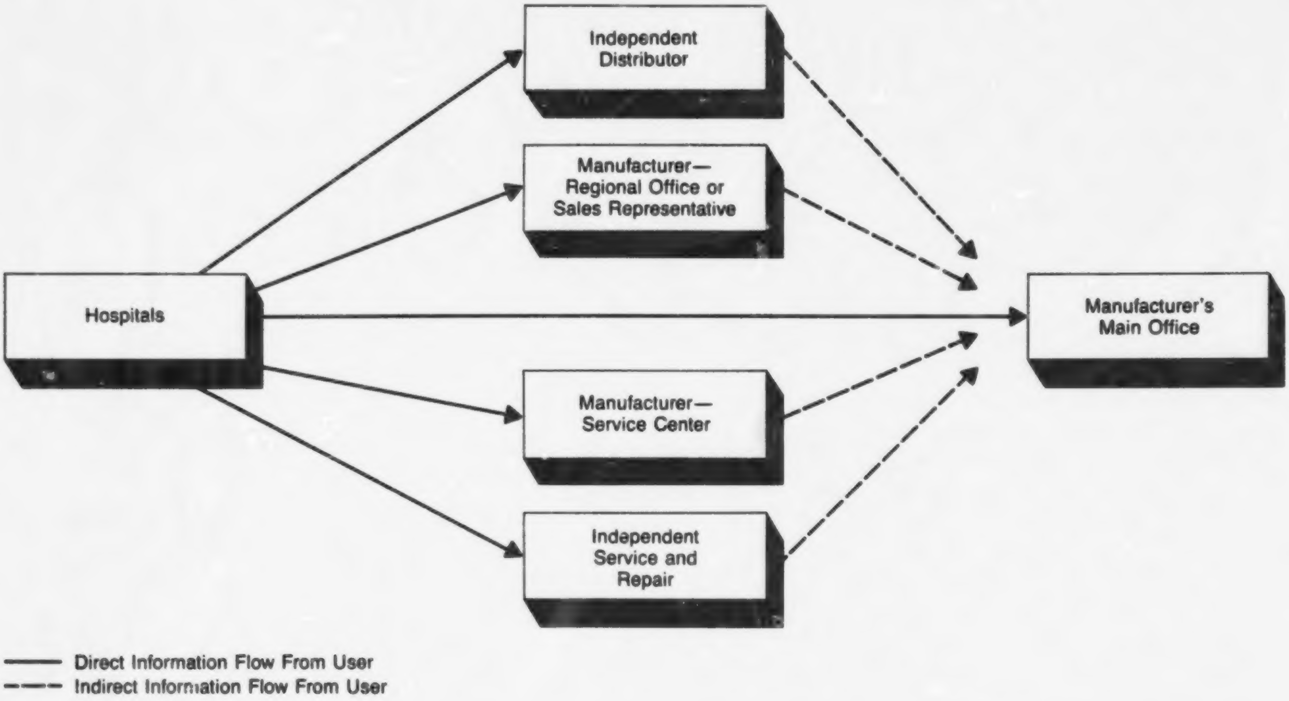
[1] The 1,175 problems that are discussed in this report represent an estimate of the information on problems with devices that we would have obtained for the 10 devices if we had sent questionnaires to the universe of all hospitals. The sampling error is 115. This means that with repeated samples of this size, one could expect that 95 in 100 times, the total number of problems would range from 1,060 to 1,290 (1,175 ± 115).

[2] FDA distinguishes between two categories of medical-device distributor. Companies that are wholly owned subsidiaries of the device manufacturers are referred to as "distributors" and are subject to the medical-device reporting rule. Companies that are not wholly owned are referred to as "independent distributors" and are not subject to the rule. About 80 percent of the confirmation forms returned to us were identified by hospitals as transmittals to a manufacturer or distributor that was a wholly owned subsidiary of the device manufacturer, and about 12 percent were transmitted to independent distributors. In the text that follows, we use the term "manufacturer" in discussing both manufacturers and wholly owned subsidiaries and the term "independent distributor" as appropriate.

Figure 3.2: Direct and Indirect Channels of Information Between Hospitals and Manufacturers on Problems With Medical Devices


Independent Distributor
Manufacturer—Regional Office or Sales Representative
Hospitals
Manufacturer's Main Office
Manufacturer—Service Center
Independent Service and Repair
Direct Information Flow From User
Indirect Information Flow From User

In our study, when reports did go out to the manufacturers, 85 percent of the hospital respondents had contacted the regional office, 68 percent the main office (some reported contacting manufacturers at both sites). Even when the hospital reported to the main office, the sales representative or repair office was the contact point almost 50 percent of the time.

The Characteristics of and Causes Attributed to the Problems That Are Reported

About 43 percent of the 1,175 individual reported problems were not covered by a manufacturer's service contract or warranty. More than 22 percent were covered by a manufacturer's or other service contract, and about 12 percent were covered by a manufacturer's warranty. Another 12 percent were covered by an exchange program, in which the vendor agrees to replace or accept the return of unsatisfactory merchandise. Approximately 11 percent of our respondents did not know whether the device was covered by a service contract or warranty.

The largest proportion of the problems associated with our sample of medical devices, 28 percent, occurred in the operating room of the hospital. This was followed by the intensive care unit, 21 percent, and the general care floor, 18 percent. About 67 percent of the problems were first discovered by nurses; physicians first discovered about 15 percent. About 73 percent of the problems were first discovered while a device was in clinical use, and slightly less than 15 percent were discovered in a pre-application test.

Asking the survey respondents to identify and describe the problems that occurred in their hospitals, we learned that they ranged from relatively minor incidents such as a broken switch or plug, having had no adverse effect on patients, to a major incident that was associated with the death of one patient, although no injury to patients was reported in 87 percent of the device problems. Injuries were associated with 9 percent of the problems; and with 4 percent of the problems, the respondents did not know if an injury was involved. Burns were the most frequent injury, at 35 percent, but no other single type of injury accounted for more than 7 percent of the reported injuries.

About 37 percent of the respondents indicated that the problem they reported could have caused a serious injury or death, while 47 percent said that it could not, and 16 percent said they did not know. Thirty-one percent of the respondents believed that there would be no adverse outcome if the problem recurred. Approximately 21 percent believed a recurrence would be life-threatening or cause permanent impairment, and 18 percent indicated that a recurrence would be serious enough to require medical intervention. In 10 percent of the problems, minor injury or discomfort not requiring medical intervention was expected if the problem were to recur, and in 20 percent of the problems, the respondents did not know how serious the outcome would be if the problem were to recur.

We also asked the hospital respondents to give their opinion of the sole cause of the problem or, if more than one cause could be identified, the most important cause. "Wear or deterioration" was selected most often, followed by defective components, a design flaw or design characteristic, and improper use or other causes related to the user. Table 3.1 shows the attributed causes identified in the order of the number of respondents who selected them.

Table 3.1: The Sole or Most Important Cause of Problems by Order of Selection

Cause	Number	Percent
Wear or deterioration	344	33
Defective components	232	22
Design flaw or design characteristic	201	19
Improper use or other user-related cause	137	13
Other	43	4
Service or maintenance problem	35	3
Packaging or sterilization	17	2
Improper labeling or interactions	14	1
Installation problem	11	1
Total	**1,034**	**98[a]**

[a] Does not equal 100 percent because of rounding.

We found that the attributed cause of a problem, whether the sole or the major cause, was related to whether or not the problem had been reported outside the hospital. When we classified the problems by attributed cause, we found substantial differences in reporting rates, shown in table 3.2. Wear or deterioration of the device, which was selected most as the sole or major cause of the problem, was reported only 41 percent of the time outside the hospital, compared to an overall outside reporting rate of 55 percent. The rate of reporting was not significantly different when the circumstances in which a device was used (such as under extreme tension or in a highly critical situation) was combined with other user-related factors (such as the application of a new therapeutic or surgical technique); this was reported outside the hospital 47 percent of the time. In contrast, 100 percent of the respondents who indicated that improper labeling or interaction with other devices or drugs was the sole or major cause said that the problem had been reported outside the hospital. Service or maintenance problems, problems caused by a design flaw or design characteristics, installation problems, and problems with defective components all ranked high in the reporting rates, although they were low in the respondents' opinions as important causes.

Table 3.2: The Sole or Most Important Cause of Problems by Whether or Not Hospitals Contacted Outside Organizations[a]

Cause	Yes	No	Number of respondents
Improper labeling or interactions	100%	0	12
Service or maintenance problems	76	24%	30
Design flaw or design characteristic	71	29	186
Installation problem	62	38	11
Defective components	62	38	226
Improper use or other user-related cause	47	53	120
Packaging or sterilization	46	54	16
Wear or deterioration	41	59	322
Other	46	54	43
Total	**55%**	**45%**	**100%**
Number of respondents	531	435	966[b]

[a] Chi square (8df) = 70.0; $p < .001$. The p (probability) value reported is an estimate of the likelihood of finding a chi-square value of this size or larger from a sample of this size when in fact there is no association in the population. In an interpretion of the size of the chi-square value, the probability stated gives a rough estimate of the chi-square value for a simple random sample.

[b] N is smaller than in table 3.1 because of missing data in the variable "outside organization contacted."

It is, thus, of major importance to note that wear or deterioration, the factor cited in about one third of all cases as the sole or most important cause of problems, was the least likely to be reported. This suggests that problems associated with many older devices may be infrequently reported outside the hospital setting.

Another factor that exerted a powerful influence on whether problems were reported is the existence of a manufacturer's warranty, service contract, or exchange program. When it was indicated that a device was covered, almost 80 percent of the respondents had reported the incidence of a problem to an organization outside the hospital. When no warranty or service contract was in effect, the reporting rate dropped, dramatically, to 41 percent.

We expected to find that problems associated with an injury to a patient or practitioner would be reported to outside organizations, but when we examined the relationship between injury and reporting, we found that a greater percentage of reports were made to external organizations when an injury did not occur than when one did. When injuries occurred, approximately 42 percent of the incidents were reported outside the hospital; when injuries did not occur, about 57 percent were reported. These data are shown in table 3.3.

Table 3.3: The Occurrence of Injury by Whether or Not Respondents Contacted Outside Organizations[a]

	Injury occurred	
Organization contacted	**Yes**	**No**
Yes	42%	57%
No	58	43
Total	**100%**	**100%**
Number of respondents	90	946

[a] Chi square (1df) = 6.2; $p < .02$.

The tendency of health-care professionals not to transmit information about device-associated problems that involve injury to patients was slightly mitigated by their responses to the question, "In your opinion, if the problem were to recur, how serious an outcome would it cause or contribute to?" Overall, 72 percent of the respondents indicated that they reported outside the hospital problems that would threaten life if they were to recur. Problems of permanent impairment and problems requiring medical intervention to prevent impairment were reported by 48 percent, and approximately 50 percent reported problems associated with minor injury or discomfort and no adverse outcome. On these important indicators, we found a positive relationship between the likelihood of reporting a device-associated problem and the probability that a recurrence would be life-threatening, as can be seen in table 3.4.

Table 3.4: The Seriousness of Outcome by Whether or Not Hospitals Contacted Outside Organizations[a]

	Organization contacted		
Seriousness if problem were to recur	**Yes**	**No**	**Number of respondents**
Life threatening	72%	28%	191
Permanent impairment or medical intervention to prevent impairment	48	52	219
Minor injury or discomfort	50	50	109
No adverse outcome	51	49	336
Total	**55%**	**45%**	**100%**
Number of respondents	470	385	855

[a] Chi square (3df) = 26.6; $p < .001$. Tau C = 0.12; $p < .001$.

We also looked at how the occurrence of injury and the status of a warranty, service contract, or exchange agreement were associated with the reporting rate. As we stated earlier, incidents were reported in about 80 percent of all cases in which some type of warranty, service contract, or exchange program was in existence, as opposed to only about 41 percent when there was none. When there was no injury and a warranty or service contract was in effect, the reporting rate was about 80 percent.

However, when an injury occurred and a warranty or service contract was in force, reporting was reduced by about 22 percent.

The Completeness of Transmitted Information

The hospitals transmitted 83 percent of their reports to outside organizations orally, and we could not verify their contents. There are no standard procedures, forms, or formats required for reporting. We assume that the information the hospitals provided to the organizations was similar to the information they gave us on the full questionnaires, but we have no information to support this assumption. Nor can we speculate on the distortion that may have occurred as oral information was passed across the various information barriers.

Influences on the Decision to Transmit Information

It seems clear that specific factors influence hospitals in the decision to transmit information about problems with medical devices: the perceived cause of a problem; the existence of a manufacturer's warranty, service contract, or exchange program; and the occurrence of an injury. Are these the same factors health-care professionals believe influence their decisions to report a problem? To find out, we asked all the hospital respondents about general factors that could contribute to or inhibit the flow of information to manufacturers, FDA, and USPC and the device experience network. We asked them to rate a number of factors on a five-point scale ranging from very strong to very weak incentives. The strong and very strong incentives are shown in table 3.5.

Table 3.5: The Percentage of Hospitals That Rated Incentives "Strong or Very Strong" to Report Problems With Medical Devices

Incentive	Report to manufacturer	Report to FDA or the device experience network
Because problem is serious	92%	81%
Protection in case of litigation	85	70
Likelihood of response from FDA or the network or assistance from manufacturer	83	56
Hospital policy to report all problems	72	58
Ease of reporting	69	60
Need for service and repair	87	[a]
Under service contract or warranty	86	[a]
To exert pressure on manufacturer	[b]	80
Not resolved satisfactorily by manufacturer	[b]	78

[a] Specific to manufacturer.

[b] Specific to FDA and the device experience network.

The majority of the respondents tended to rate most of the factors we presented them as strong or very strong incentives to contact the manufacturer, FDA, or the network. The factors that elicited the highest levels of strong or very strong response related to the seriousness of the problem, 92 percent; the need for service and repair, 87 percent; and the fact that the device was under a service contract or warranty, 86 percent. The seriousness of the problem also elicited the highest positive response as an incentive to contact the device experience network, at 81 percent. Exerting pressure on the manufacturer to rectify a problem was also rated by 80 percent of the respondents as a strong or very strong reason to contact FDA or the network.

We also asked the respondents to rate a number of "disincentives" on the same five-point scale. The overall percentages were somewhat lower for disincentives than for incentives. The disincentives with the three highest ratings, in terms of the percentage of respondents rating the factor as a strong or very strong incentive not to contact the manufacturer, were the following:

1. the problem is not related to device malfunction (50 percent),

2. the difficulty of reporting (38 percent), and

3. the unlikelihood of receiving assistance from the manufacturer (36 percent).

The three highest-rated disincentives to contact FDA or the device experience network were, in the same terms,

1. the satisfactory resolution of the problem by manufacturers (62 percent),

2. being unaware that I could report to USPC or the network (53 percent), and

3. being unaware that I could report directly to FDA (52 percent).

We found (in table 3.5) that the strongest incentive for reporting a problem, in terms of the respondents' own perceptions, was the seriousness of the problem. This finding is not consistent with our finding (in table 3.3) that the respondents tended to not report problems resulting in an injury to the patient or practitioner. The logic of our expectation that problems resulting in injury would have a greater likelihood of being reported than problems not resulting in injury was reinforced by the large proportion of respondents who ranked the seriousness of a problem as a strong or very strong incentive to report it outside the hospital. But when we examined the relationship between reporting and injury only for the respondents who ranked the seriousness of the problem as a strong or very strong incentive to report it to the manufacturer, we found a greater tendency (in percentages) not to report incidents involving injury (see table 3.6).

Table 3.6: Actual Seriousness as an Incentive to Report Device-Related Problems to Outside Organizations[a]

	Injury occurred	
Organization contacted	**Yes**	**No**
Yes	36%	57%
No	64	43
Total	**100%**	**100%**
Number of respondents	81	811

[a] Includes only cases in which seriousness was rated as a strong or very strong factor in reporting to the manufacturer. Chi square (1 df) = 12.7; $p < .001$.

To try to explain the discrepancy, we examined the relationship between reporting and injury, controlling for both the attributed cause and the seriousness of the problem as incentives to report to the manufacturer. What we found were similar rates of reporting (65 percent) for cases in which an injury did and did not occur. Table 3.7 shows that there is no relationship between reporting and injury for cases in which respondents ranked problem-seriousness as a strong or very strong incentive to report to the manufacturer and the incident was identified as related to defective components, improper labeling or instructions, a design flaw or design characteristic, packaging or sterilization problems, or installation problems.

Table 3.7: Actual Seriousness as an Incentive to Report Device-Related Problems to Outside Organizations, Controlled for Attributed Cause and Seriousness of the Problems[a]

	Injury occurred	
Organization contacted	**Yes**	**No**
Yes	65%	65%
No	35	35
Total	**100%**	**100%**
Number of respondents	31	352

[a] Includes only cases in which seriousness was rated as a strong or very strong factor in reporting to the manufacturer and cases in which the incident was identified as manufacturer-related. Sole or major cause of problem was defective components, improper labeling or instructions, design flaw or design characteristic, packaging or sterilization problems, or installation problems. Chi square = 0; p not significant.

This suggests that it is whether or not the type of cause attributed to a problem is related to the manufacturer—over and above injury and seriousness—that plays the greatest role in whether incidents associated with medical devices are reported outside the hospital. That is, the problems that are the most likely to be reported are manufacturer-related rather than user-related or those in which the device is under some sort or warranty, service contract, or exchange agreement. Whatever the determining factor, however, the fact remains that only 51 percent of the 1,175 problems with medical devices identified in our survey were made known to any organization outside the hospital in which they occurred.

Summary

In examining the results of our survey on the transmission of information about problems associated with the use of medical devices from hospitals to manufacturers, FDA, and third-party organizations, we found that only 593, or 51 percent, of the 1,175 problems hospitals identified were reported to any organization outside the hospital where they occurred. About 92 percent of the total number of reports were sent to the manufacturer or independent distributor of the device; about 8 percent were sent to "other organizations," such as the Emergency Care Research Institute. In less than 1 percent of the cases, the problem was reported directly to FDA or USPC and the device experience network.

When the report was directed toward the manufacturer, 85 percent of the contacts were made to a firm's regional offices, 68 percent to the main office (in some cases, both were contacted). Where the manufacturer was the principal target, the information flow was often not direct. One or more intermediaries such as independent distributors and sales representatives often came between a hospital and a manufacturer's headquarters, and a blockage or breakdown in the flow of information could and did occur. Thus, report receipt is diffused, not centralized.

The majority of the problems reported in our survey (73 percent) were first discovered while a device was in clinical use. They ranged from relatively minor incidents that had no adverse effect on patients to a major incident that was associated with the death of a patient. Although no injury was reportedly related to 87 percent of the device problems, about 37 percent of the respondents indicated that their reported problems could have caused serious injury or death. When hospital respondents were asked to give their opinion of the sole or most important causes of problems, wear or deterioration of a device was cited in about one third of all cases. We discovered that the cited cause of a problem was related to whether or not the problem was reported outside the hospital, finding, for example, that wear or deterioration was the least likely to be reported. This suggests that problems associated with older devices may not often be reported outside the hospitals.

Another factor exerting a powerful influence on reporting was the existence of a manufacturer's warranty, service contract, or exchange agreement. When devices were covered, the reporting rate was almost twice that of devices that were not covered.

The occurrence of an injury associated with the use of a device was found to be inversely related to reporting. We expected that injury would lead to a higher rate of reporting. We found, however, that when injury occurred, the rate at which problems were reported outside the hospital was only 42 percent, compared to 57 percent when injury did not occur.

Finally, we found that it is the type of cause of the problem—over and above injury or the seriousness of the problem—that influences whether incidents are reported or not. That is, problems related to the device itself, especially those in which the device is under some sort of warranty or service arrangement, are more likely to be reported than problems related to its user.

Although we sought to determine whether hospitals transmitted information about the nature, cause, and consequences of problems with medical devices, we found that about 83 percent of the reports from hospitals to outside organizations were transmitted orally. No standard reporting procedures, forms, or formats are required. Therefore, we can only speculate on the information, and the distortion in the oral information, that was passed along. Overall, whatever the determining factor, whatever the destination of the report, and whatever the form or contents of the message, only about half the device-associated problems identified in our survey were reported to any organization outside the hospital in which they occurred.

Chapter 4

The Response to Information on Problems Associated With Medical Devices

How We Approached Our Second Objective

In this chapter, we focus on information as a communications network and on the capacity of the network to satisfy the need for early warning about medical-device problems. Our second objective was concerned with the receipt of information from hospitals and the range and frequency of the actions everyone in the communications network takes in response to device-associated problems. We established the four questions listed in chapter 1:

1. What is the range of responses available to hospitals, manufacturers, FDA, and other related organizations?

2. What is the relative distribution of types of responses they make?

3. What are the characteristics of the responses to the different types of problems associated with devices?

4. What factors are thought to influence the decision to respond to these problems?

The questions we included in our hospital survey enabled us to describe the hospitals' range of responses to problems within the hospitals. In addition, the questionnaire included a number of questions on the transmission of information outside the hospitals.

To describe the responses of others in the communications network, we tracked the information with the use of a one-page confirmation form we sent to the organizations that our survey respondents indicated had been notified of a problem. The limited number of cases in which hospitals contacted FDA, the Emergency Care Research Institute, and other organizations and reports were located precludes our complete description of the responses of these organizations to hospital transmittals. Therefore, the discussion in this and the following sections provides a brief descriptive overview of the information transmitted and received primarily by manufacturers and independent distributors. (Appendix IX contains a detailed discussion of our methodology for confirming hospital reports to device manufacturers, and appendix X contains our confirmation form.)

Overview

The hospitals were able to provide enough information to enable us to track only 436 of the 543 reports sent to manufacturers and independent distributors.[1] But manufacturers could find only 139 of these, or 32 percent, in their files. That 86 percent of the 543 reported transmissions were oral, and therefore without a "paper trail," could partially account for this finding. When all the hospitals' reports are considered, 83 percent of the 593 reports were oral. However, the data suggest that the structure and operation of the indirect reporting route, the presence or absence of a warranty or service arrangement, and the perceived cause of a problem also affect this segment of the information flow.

The manufacturers were able to identify fewer reports transmitted indirectly, through intermediaries: they verified only 28 percent of the hospital reports sent to regional offices but 49 percent sent to their main offices. Repair and service work performed under warranty often requires the approval of the main office for payment, and written records were more likely to be established in those cases. Fifty-five percent of the contacts could be verified when the device was under warranty, versus 34 percent when no warranty or service agreement existed between user and manufacturer. The manufacturers also said that the nature and quality of the information they received from intermediaries varied. In the extreme case, for example, no record at all may be kept when the device is sold outright to dealers or rental agencies and the manufacturer is not in contact with the users or when the company sales or service representative satisfactorily resolves the problem. They could verify only 4 of 49 problems that were reportedly transmitted to independent distributors.

We also found that the cause of a problem, whether the sole or major cause, was related to the ability of manufacturers to locate the message about the problem in their files. They located only 20 percent of the reports in which a problem was attributed to improper use or other user-related causes. When the sole or most important cause of the problem was cited as defective components, about 54 percent of the hospital reports were located. (See table 4.1.) We do not know whether these findings stem from communications problems with the sender, the oral nature of the message, the discretion of the receiver, or the characteristics of the problem with the device.

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[1] We were unable to track the remaining 20 percent (100 reports). Approximately one third of these did not contain sufficient information, another third were directed to other organizations such as hospitals and insurance companies, and another third were received after we analyzed the data. We were able to locate addresses and send confirmation forms for only 37 percent of the transmittals hospitals reportedly sent directly to independent distributors. We sent confirmation forms to the manufacturers of the devices in the remaining cases. The responses of both manufacturers and independent distributors to problems are included in the analysis that follows.

Table 4.1: Manufacturers Locating Reports by Sole or Most Important Cause of Problem[a]

	Report located by manufacturer	
Cause	**Yes**	**No**
Defective components	54%	46%
Design flaw or design characteristic	38	63
Wear or deterioration	37	63
Packaging or sterilization	31	69
Improper use or other user-related cause	20	80
Installation problems	20	80
Improper labeling or interactions	16	84
Service or maintenance problems	0	100
Other	24	76
Total	**38%**	**62%**
Number of respondents	125	204

[a] Chi square (8df) = 21.5; $p < .01$.

The Range and Distribution of Responses to Hospital Reports

Hospitals have a number of internal ways of responding to problems with devices. We asked them what they did besides contacting other organizations. About 85 percent of the time, the hospitals did take action internally, 33 percent indicating that they repaired or replaced a defective component and 23 percent indicating that they removed the device from service and informed hospital departments about the problem. Other actions were taken much less frequently.

We found that the internal responses were related to the perceived cause of a problem and did, for the most part, strive to rectify it. For example, 69 percent of the hospital respondents who cited wear or deterioration of a device as the sole or major cause of the problem said that the device was repaired, replaced, or removed from service. About 61 percent citing improper use as the sole or major cause indicated either that in-service training programs on proper use were improved or instituted or that hospital departments were informed about the problem. About 85 percent who cited defective components indicated that the device was repaired, replaced, or removed from service or that hospital departments were informed. These findings indicate that whether or not hospitals inform other organizations, in many cases they take their own specific actions.

FDA was notified of only 3 of the 139 problems for which the manufacturers were able to locate a hospital report. The most prevalent response of the manufacturers was to repair or replace a device, which they did 52 percent of the time. For another 18 percent of the problem reports, the manufacturers took no action at all. For the 17 percent of manufacturer actions classified as "other," the response tended to be specific to a particular situation—for example, conducting a metallurgical investigation, installing a faster device, or writing the hospital. Supplemental instructions for the use of devices were distributed 4 percent of the time, and a manufacturer's design unit was notified 7 percent of the time.

The hospitals were able to provide us enough information to track only 38 of the 49 reports sent to independent distributors. We tracked 41 percent of the reports by sending the confirmation forms to the device manufacturers, and 37 percent were tracked directly to the independent distributors. Manufacturers were able to locate only 20 percent of the problem reports in their files. Their responses in all cases were to repair or replace the devices. Independent distributors were able to confirm 7 of 18 problem reports. Three problems were reported to manufacturers, and in the four other cases, the devices were repaired. Neither the device manufacturers we contacted in lieu of the independent distributors nor the independent distributors we contacted directly notified FDA about any of the reported problems.

Because reviewing the manufacturers' good manufacturing practices complaint files was, until December 1984, one of FDA's main sources of information, including the hospitals' transmittals in these files is critical to the flow of information. Only 11 percent of the manufacturers reported finding a hospital transmittal in their good manufacturing practices complaint files. Many commented that reports were not filed in them when the response to a problem was routine service or repair, because it is not required, although the manufacturers in our sample admitted that they have discretion about deciding what constitutes a complaint. In one case in which a patient died, the transmittal was not in the complaint file because it had not been officially registered with the company.

Given the importance of the complaint files, we sent FDA a random selection of written but unidentified hospital descriptions of problems and asked for an opinion of whether each problem would qualify as a good manufacturing practices complaint if the manufacturer had received the report.[2] We asked FDA to assume that the problem occurred when the device was in use with a patient—that is, in a "worse case" situation. Then we compared the FDA assessment with what was found in the files on problems experienced during clinical use and in the good manufacturing practices complaint files. Twenty-two cases met all these criteria: they were in the sample of problem descriptions we sent to FDA, the problems occurred in clinical use, and the manufacturers found the transmittals and indicated whether or not they were entered in the complaint file. FDA's assessment was the same as that of the manufacturers in only about a third, or 36 percent, of these cases. The remaining 64 percent were all cases in which the report was not in the complaint file but FDA thought it should have been. No report was in the complaint file that FDA thought should not be there.

FDA's possible responses to reported problems range from the punitive actions set forth in sections 516 and 518 of the Food, Drug, and Cosmetic Act, added by the Medical Device Amendments of 1976, such as seizing or recalling a device, to less extreme, more informal responses designed to influence a manufacturer to take some corrective action, such as simply discussing a problem with a manufacturer or sending a regulatory letter of notification that more formal actions may follow. (See table 4.2.) The hospitals reported only two problems directly to FDA. No record was found at FDA headquarters of the one regarding a death. The other was found, and FDA had taken an action (the problem was noted in the firm's file for discussion during the next site inspection).

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[2] These were the problem descriptions provided by hospital respondents in question 1 of our hospital questionnaire (see appendix VIII).

Table 4.2: Potential FDA Responses to Problems Reported on Devices

Remedy	Problem	Potential action
Notification	Device presents an unreasonable risk of substantial harm to public health	Health professional who prescribed or used the device must notify individuals treated with it of the risk involved and of any actions that may be taken to reduce the risk
Repair, replacement, or refund	Notification would not by itself eliminate unreasonable risk	Manufacturers must —repair the device so it does not present an unreasonable risk of substantial harm, —replace it with a like or equivalent device that conforms to the requirements of the act, or —refund the purchase price
Seizure	Device constitutes substantial deception or an unreasonable or substantial risk of illness or injury	FDA may promulgate a regulation banning the device, enjoining its manufacture and use

The Emergency Care Research Institute was able to verify only one of the five reports hospitals reportedly made to it. The Institute's response in this case was to contact the manufacturer, conduct a full investigation, and resolve the problem with the hospital. The one other third-party monitoring organization, the Centers for Disease Control, did not return our confirmation form.

The Characteristics of and Factors That Influence Responses to Hospital Reports

The three factors we thought would have the greatest influence on the responses manufacturers made to hospitals' reports of problems were warranty or service arrangements, the cause of a problem as perceived by the manufacturers and distributors, and the seriousness of the problem. No consistent pattern emerged with respect to the type of service arrangement between the manufacturer and the hospital—that is, whether the device was covered by a warranty or by a service contract or whether no such arrangement existed. However, the manufacturers were more likely to determine that no action was needed (30 percent) when a warranty or service arrangement did not exist than they were when one did (18 percent).

When we asked the manufacturers and independent distributors their opinion of the cause of the reported problems, 27 percent indicated the causes were manufacturer-related (defective components, design flaws, design characteristics, improper labeling, or sterilization or packaging problems), 18 percent user-related (error, lack of training, misuse, or conditions of use), 14 percent wear or deterioration, and 7 percent device maintenance. The manufacturers and independent distributors attributed the problems to "other" causes (custom software, installation, could not verify, among others) in 20 percent of the cases and did not know the cause of the problem in 14 percent.

Not unexpectedly, they decided more often that no action was needed when they perceived the cause of a problem as user-related (36 percent) than when they perceived it as manufacturer-related (11 percent). The manufacturers and distributors viewed none of the hospital reports they forwarded to FDA as manufacturer-related problems.

Two questions from the hospital survey were intended to be indicators of the seriousness of problems: whether or not an injury occurred and whether or not the problem could have caused or contributed to a serious injury or death. The results of crosstabulating these questions with the actions taken by the manufacturers and distributors are shown in table 4.3.

Table 4.3: Actions Manufacturers and Independent Distributors Took by the Seriousness of Problems[a]

	Action taken				
Action	**In all cases**	**When injury did occur**	**When injury did not occur**	**Could have caused death or injury**	**Could not have caused death or injury**
Determined no action needed	18%	57%	15%	20%	10%
Repaired or replaced device	52	11	56	39	76
Issued problem alert	0	0	0	0	0
Recalled product	1	0	1	0	0
Reported to FDA	2	11	0	3	0
Revised label	1	0	1	1	0
Distributed supplemental instructions for proper use	4	0	4	5	0
Reported to company design and engineering unit	7	0	8	9	6
Other	17	21	16	23	7
Total	**100%**	**100%**	**101%[b]**	**100%**	**99%[b]**
Number of respondents	166	9	149	70	71
Number of cases	136	131		117	

[a] Percentages are based on the number of responses.

[b] Does not add to 100 percent because of rounding.

The occurrence of an injury did not appear to guarantee that manufacturers would act. On the contrary, their most frequent response was to take no action. In 57 percent of the cases in which an injury occurred, the manufacturers determined that no action was necessary. We found that the manufacturers reported problems to FDA in only 11 percent of the cases in which an injury occurred. When the reported problem could have but did not cause or contribute to a serious injury or death, the most frequent response was to repair or replace the device (39 percent).

The existence of a manufacturer's warranty or service arrangement did influence manufacturers and distributors to include a hospital report of a problem in the good manufacturing practices complaint file. When a warranty or other service arrangement was in effect, about 18 percent of the reports were entered in the complaint file, compared to only 4 percent when it was not.

The manufacturers' perceptions of the cause of problems was also related to whether a report was filed in the complaint file. About 70 percent were included when they perceived problems as user-related, only 15 percent when they perceived them as device-associated. (See table 4.4.) As we have shown, compared to manufacturer-related problems, user-related problems were often not acted on and more likely to be included in the complaint file. This suggests that manufacturers tend to use the good manufacturing practices complaint file as a listing of user-related device problems.

Table 4.4: Manufacturers' Perceptions of the Cause of Problems by Whether or Not Hospital Reports Were in Their Good Manufacturing Practices Files[a]

	Problem cause	
Problem filed	**User-related**	**Device-related**
Yes	70%	15%
No	30	85
Total	**100%**	**100%**
Number of respondents	13	29

[a] Chi square = 10.2; $p < .01$.

Finally, when we looked at the relationship between injury to patients and practitioners and the good manufacturing practices complaint file, we found that 41 percent of the reports involving injury were included in the file but only 11 percent when an injury did not occur. (See table 4.5.) However, finding that less than half of all incidents for which the manufacturers were able to locate the hospital reports were included in the manufacturers' complaint files raises doubts about the usefulness of these files to FDA as an indicator of the extent and characteristics of device-associated problems.

Table 4.5: The Occurrence of Injury by Whether or Not Hospital Reports Were in Manufacturers' Good Manufacturing Practices Files[a]

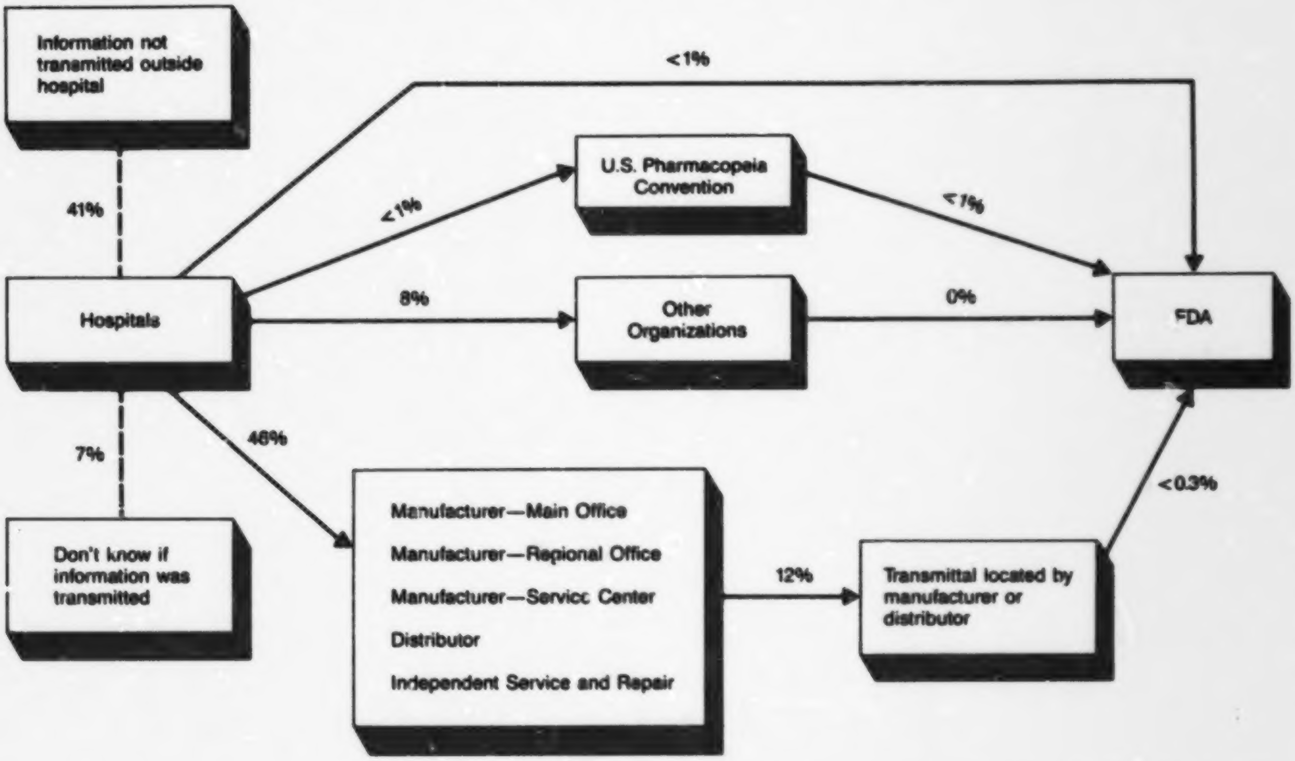
	Injury occurred	
Problem filed	**Yes**	**No**
Yes	41%	11%
No	59	89
Total	**100%**	**100%**
Number of respondents	18	213

[a] Chi square = 9.9; $p < .01$.

Early Warning Information Flow

FDA can receive an early warning of problems with medical devices only if information flows effectively from the hospitals along the various channels of the communications network. The four main channels to FDA are (1) direct, (2) through USPC, (3) through third-party monitoring organizations, and (4) through device manufacturers. For the first one, we found that no information flowed into the network for at least 41 percent of the incidents hospital personnel identified (perhaps more if "don't knows" are accounted for). Second, the channels from the hospitals directly to FDA and through USPC to FDA were very seldom used: the hospitals sent less than 1 percent of the problems to FDA by these channels. Third, the channel through third-party organizations provided no information to FDA, even though slightly more than 8 percent of the hospital reports were sent into this channel. Fourth, only the channel through the manufacturers accounted for many reports. Information on 46 percent of the hospital incidents flowed into this channel, although less than 1 percent were ultimately reported to FDA. (See figure 4.1.)

Figure 4.1: The Flow of Information on Medical Devices From Hospitals to FDA


Information not transmitted outside hospital
<1%
U.S. Pharmacopeia Convention
41%
<1%
<1%
Hospitals
8%
Other Organizations
0%
FDA
7%
46%
<0.3%
Manufacturer—Main Office
Manufacturer—Regional Office
Manufacturer—Service Center
Distributor
Independent Service and Repair
Don't know if information was transmitted
12%
Transmittal located by manufacturer or distributor

[a] Percentages show flow based on 1,175 device-associated problems reported to GAO by hospital personnel and equal more than 100 percent because, in some cases, problem reports were transmitted to more than one organization.

Most importantly, FDA knew of less than 1 percent of the medical-device problems in hospitals. About 9 percent of these problems were associated with injuries, and 37 percent were associated with serious injury or potential death. Taking these findings together, we conclude that important problems with medical devices were unknown to FDA because the communications network between the hospitals and FDA did not work very well. The pattern of our findings indicates that two obstacles would have to be overcome: a moderate reporting rate and low transmission rates.

Hospital personnel report only slightly more than half of the incidents they know about. There may be no need to report noninjurious incidents, but important problems are underreported. Why is the reporting rate not higher? It may be that a large proportion of hospital personnel are not yet oriented to the idea of an early warning system. This is understandable in a large, decentralized system of relatively recent origin. More than 50 percent of the health-care professionals did not know they could report problems directly to FDA or indirectly through USPC. And they associate reporting through the manufacturer with warranties and service arrangements. The primary incentives for contacting manufacturers' representatives are the seriousness of a problem and repair and replacement, not warning FDA of possible problems. Our findings suggest that improving the reporting rate will require steps to increase health-care professionals' awareness of FDA's need for early warning information.

The rates at which hospital reports are transmitted is of concern. The first three channels are of little consequence, because so little information enters them, but the manufacturer channel is different, because in a funneling effect, it takes in a relatively large number of reports but transmits few. Beginning with the 1,175 problems reported by hospitals in our study, 593, or 51 percent, went outside the hospital; 543, or 46 percent, went to manufacturers and independent distributors; only 139, or 12 percent, could be located by the manufacturers and independent distributors in their files; 3, or less than 1 percent, could be located by FDA.

Messages may be lost in a variety of ways in the complex manufacturer channel. Some persons handling reports in this channel may not see themselves as part of a communications network, and reports may stop at a number of points—at a manufacturer's or an independent service center, at a regional office, or at an independent distributor's offices. For example, we know that a response to a report along this channel is more likely to be a repair or replacement of the device than a forwarding of the report in the direction of FDA. It is evident that both repair and replacement and early warning are two possible uses of communication, but for the incidents in our study, the manufacturer channel did not serve the early warning function very well.

Moreover, oral messages without written follow-up may satisfy the need to get devices repaired or replaced but probably increase the chance that the information will not be forwarded or that it will be distorted. Sending messages orally may defeat the early warning purpose.

Another possible difficulty with the manufacturer channel is that too many reports that should be transmitted to FDA may be filtered out. This is suggested by the manufacturers' placing fewer problem reports in the good manufacturing practices complaint files than FDA would. The recently implemented medical-device reporting rule will probably result in more information getting through to FDA, although the manufacturers may still disagree on how to define a problem for reporting purposes.

The transmission rates might be increased by improving communication in the manufacturer channel or by making greater use of less complex alternative channels. To build up the alternatives, health-care professionals would have to become aware of the possibilities and change their behavior. It would probably be easier to improve communication along the manufacturer channel, but it would probably have to be simplified. A message handled by just three persons sequentially at three locations—the hospital, the distributor, and the manufacturer—with a 50-percent chance of being transmitted by each person has an overall chance of being transmitted to FDA of 12.5 percent. If there are six persons in the chain, this chance drops to less than 2 percent. Even if the probability of transmission from each person is very high, the overall chance that the message will get through may be relatively low. A message with a 90-percent chance of getting through each of six persons will have only about a 50-percent chance of reaching FDA.

Therefore, to increase the transmission rate through the manufacturer channel, the probability of transmission by each person in the network should be increased and the number of persons should be decreased. The first step has already been taken, because the medical-device reporting rule is intended to increase the probability that messages will be transmitted from manufacturers to FDA. But we believe the reasons manufacturers and distributors were aware of only 12 percent of the incidents known to hospitals are that too many persons handled messages before they reached a manufacturer's main office and many of the reports were oral.

Summary

Whether or not the hospitals contacted outside organizations about their problems, they took internal actions 85 percent of the time. Further, in our survey, hospitals indicated that of the 593 reports that were transmitted to outside organizations 543, or 92 percent, were sent to manufacturers and independent distributors. Hospitals were able to provide enough information to enable us to track 436, or 80 percent, of these reports. However, manufacturers and independent distributors were able to locate only 139, or 32 percent, of these 436 reports in their files. A number of factors may account for this: (1) 83 percent of the 593 problems transmitted by hospitals were transmitted orally, (2) a number of intermediaries sat between the hospitals and the manufacturers' headquarters, (3) reports were fewer when there was no warranty, (4) the manufacturers could find fewer reports of problems the hospitals perceived as user-related than those they perceived as related to a device or its components, (5) the manufacturers have discretion in defining what constitutes a complaint, and (6) they were likely to put more user-related than device-associated reports in good manufacturing practices complaint files.

FDA was notified of only 3 of the 139 problems for which manufacturers and independent distributors were able to locate the hospital report. The most prevalent response manufacturers made to the reported problems (52 percent) was to repair or replace the device. In 18 percent of all cases, the manufacturers took no action. The manufacturers found only 11 percent of the hospital reports in their good manufacturing practices complaint files. A comparison of FDA's assessment of criteria for what to put in these files with what the manufacturers actually put in them showed a great deal of disagreement between the two.

Manufacturers were more likely to determine that no action was needed when a warranty or service arrangement did not exist, when they perceived that the cause of a problem was user-related, and when an injury occurred. Manufacturers forwarded to FDA only 11 percent of the reports of problems in which injury occurred. The same three factors were related to manufacturers' placing hospital reports of problems in their good manufacturing practices complaint files. In our survey, they found more reports in these files when a warranty or other service arrangement was in effect, when they perceived problems as user-related, and when injury occurred. However, we doubt the value of these files to FDA as an indicator of the extent and characteristics of device-associated problems, since less than half of the hospital reports the manufacturers found were found in them.

Our findings make clear the weaknesses that exist in each link of the network of communication FDA uses to ensure the safety and effectiveness of medical devices. Solutions to rectify these weaknesses should consider the network as a whole rather than trying to repair or strengthen a single link within it.

Alternative Approaches and Promising Practices for Postmarketing Surveillance

How We Approached Our Third Objective

Our third objective was to examine how organizations conduct postmarketing surveillance for selected goods and services other than medical devices. We established the two evaluation questions given in chapter 1:

1. How do federal agencies with similar responsibilities for monitoring potentially hazardous technologies collect information?

2. What other methods and specific practices might FDA use to improve data quality and usefulness?

We limited our review to federal agencies, since other federal efforts are more likely to be directly transferable to FDA than those operating in either the private sector or other nations.[1]

How Other Agencies Monitor Potentially Hazardous Technologies

In our review of the data collection methods employed by agencies with hazard-monitoring responsibilities, we identified two primary sources of information—a census of all incidents or individuals and a sample of incidents or individuals. For each of these sources, data could be collected through either voluntary or mandatory reporting. (See table 5.1.) The characteristics of the source and method have important implications for the quality and usefulness of the information obtained through them.

Table 5.1: Typology of Monitoring Systems for Potentially Hazardous Technologies

	Information source	
Collection method	**Census**	**Sample**
Voluntary	Device experience network: Census with voluntary reporting	FDA: Sample with voluntary reporting
Mandatory	FDA, medical-device reporting rule: Census with mandatory reporting	Congress: Sample with mandatory reporting

In a complete census, all events from a total or relevant population of individuals or events are reportable. In a sample, reports are obtainable from only a small percentage of the total population. A probability sample is often the most useful for monitoring purposes. When a probability sample is drawn, each member of the relevant population has a known chance or probability of being included in it; the members are drawn randomly. Reports are thus requested and accepted only from participants that have been selected under systematically controlled circumstances.

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[1] See appendix XI for a discussion of the methodology we used for objective 3 and a complete list of the systems managed by the federal agencies we reviewed.

In voluntary reporting, the decision to report an adverse event has no requirement in law and is spontaneous, in that any member of the population affected by the product or technology being monitored, whether a total population or a sampled population, may submit a report on any problem experienced at any time.

In mandatory reporting, all detected adverse events of a certain type must be reported to the administering agency, either from the entire population or from a specific sample. The types of events to be reported, the information to be included, the persons who must do the reporting, and the time when the reports must be submitted are typically specified in law. The intended result is a complete listing of events of a certain type considered important for monitoring hazards associated with the use of a product or technology. In table 5.2, we present the sponsoring agency, its method of collection, and its sources of information for 15 specific reporting systems.

Table 5.2: The Characteristics of 15 Hazardous-Technology Monitoring Systems

System	Sponsor	Method of data collection	Information source	Remarks
Airline Consumer Complaint Information System	Dept. of Transportation, Office of the Secretary	Voluntary	Census	Collects reports from any consumer concerning any complaint (baggage loss, overbooking, and so on)
Annual Survey of Occupational Injuries and Illnesses/Supplementary Data System	Bureau of Labor Statistics and Occupational Safety and Health Administration	Mandatory	Probability sample	State agencies mail questionnaires to approximately 280,000 employers annually; employers transfer data from mandatory records to the questionnaire; OSHA regulations require their participation in the survey
Aviation Safety Reporting System	Federal Aviation Administration	Voluntary	Census	National Aeronautic and Space Administration administers the system under contract with a private research firm; aviation community encouraged to report safety-related problems; additional information collected by telephone follow-up
Fatal Accident Reporting System	National Highway Traffic Safety Administration	Mandatory	Census	All 50 states collect basic data on all highway fatalities and transfer it electronically to NHTSA; primary information source is police accident reports
Licensee Event Report System	Nuclear Regulatory Commission	Mandatory	Census	Licensed nuclear power plant operators and other licensees required to report adverse events such as overexposures, shutdowns, and deviations from a plant's technical specifications directly to NRC
Mine Accident, Injury, and Illness Report System	Mine Safety and Health Administration	Mandatory	Census	Mine owners and operators required to report occupational injuries and illness directly to MSHA
National Accident Sampling System	Traffic Safety Administration	Mandatory	Probability sample	Police accident reports sampled within regions and police departments; research teams collect under contract by physical inspections of vehicles and the accident scene
National Electronic Injury Surveillance System	Consumer Product Safety Commission	Voluntary	Probability sample	65 hospital emergency rooms collect information under contract on consumer product-related emergency room visits; additional information collected by telephone and on-site follow-up
National Emissions Data System	Environmental Protection Agency	Mandatory	Census	State agencies collect point-source data in questionnaires and site visits; point sources emitting more than 100 tons of any specified air pollutant per year must report
National Occupational Exposure Survey	National Institute of Safety and Health and Occupational Safety and Health Administration	Mandatory	Probability sample	Data collected from visits to approximately 5,000 work sites allow estimations of the number of employees exposed to potentially hazardous chemicals in work settings
National Response Center	U.S. Coast Guard	Primarily mandatory	Census	Transporters and operators of storage facilities of hazardous materials required to report to Environmental Protection Agency and other agencies for followup
Near Mid-Air Collision Reporting System	Federal Aviation Administration	Voluntary	Census	Aviation professionals and general aviation pilots encouraged to report near midair collisions in which they are involved; possible causes emphasized; field inspectors follow up reports

System	Sponsor	Method of data collection	Information source	Remarks
Railroad Accident-Incident Reporting System	Federal Railway Administration	Mandatory	Census	Railroad companies required to report all accidents and injuries directly to FRA
Recreational Boating Accident Reporting System	U.S. Coast Guard in conjunction with the states	Mandatory	Census	Recreational boat owners and operators required to report fatal and nonfatal accidents directly to U.S. Coast Guard or designated state agencies
Service Difficulty Reporting System	Federal Aviation Administration	Mandatory	Census	Air carriers, general aviation repair stations, air taxi companies, and manufacturers required to report, directly to FAA, components failures that threatened or could threaten airworthiness

Specific Practices and Methods FDA Might Use

Mandatory Reporting

Mandatory reporting such as that established by the medical-device reporting rule can produce a potentially complete sampling of the events deemed important for monitoring a hazardous product or technology. Mandated reporting can avoid many of the sources of underreporting in a voluntary system, because the resulting data more accurately reflect the nature and extent of the problems associated with the hazards. Several programs with mandatory reporting require the submission of incidence-of-use data or other information necessary for calculating rates at which adverse events occur and, thus, assessing degrees of risk. For example, the Department of Transportation requires air carriers to report a variety of operations data, including total number of flights, flight hours, miles flown, and passengers carried. Similarly, the Federal Railway Administration requires railroads to report the number and types of accidents and incidents that occur, the number of person-hours worked, and the number of train-miles run. When both voluntary and mandatory data are collected, the degree of risk associated with the use of a potentially hazardous technology can be assessed with reasonable accuracy.

All the systems with mandatory reporting that we reviewed required that reports on adverse events come from the source experiencing the event or the institution operating or using the technology entailed in the event. In our survey on medical devices, however, almost half the device-related problems experienced in hospitals were not reported to manufacturers, distributors, or FDA. About 72 percent of the reports hospitals made to the manufacturers' regional offices never reached the main office, and 69 percent of the reports made to manufacturers and distributors were not recorded in a central file for FDA's review. Requiring census reporting, if it is possible, or a probability sample for collecting data would reduce underreporting and yield data of sufficient quality to make both qualitative and quantitative analysis possible. However, mandatory hospital reporting would strengthen only one element of the communications network without addressing others such as centralization, message format, and the discretion to define problems that are also of great importance, unless it expressly included them.

Probability Sampling

Reporting systems based on probability sampling, such as the national accident sampling system (NASS) of the National Highway Traffic Safety Administration and CPSC's national electronic injury surveillance system (NEISS), have produced statistically valid data for quantitative analysis to provide feedback, encourage further reporting, and support regulatory decisionmaking. Under NEISS, for example, the promulgation of performance standards has involved products similar to many class II devices for which FDA is required to establish performance standards.

If FDA required reporting in written form from every element in the communications network, including hospitals, distributors, and manufacturers' regional and main offices, in addition to the information manufacturers transmit through the medical-device reporting rule, the ability of the network to ensure that a problem finds its way through the system to the proper point would be greatly improved. The mandate need apply not to the entire universe of health-care professionals and associated manufacturers and support personnel but, rather, to a probability sample of these individuals. Alternatively, the information from the current reporting requirement could be supplemented with information from a statistically valid probability sample of hospitals, possibly under contract with FDA and reporting to device manufacturers.

In 1980, FDA tested this concept. It demonstrated the health experience reporting system, intended to expand hospital procedures for recognizing device failures and mislabeling and reporting them to FDA and manufacturers. The system was designed to use a stable probability sample of U.S. hospitals under contract with FDA. The specific data collection practices, patterned after those used in NEISS, were demonstrated at two hospitals. Data on adverse events were collected, encoded, and entered into a computer facility from terminals within the two participating hospitals.

The system could have provided FDA with more and better information about problems with medical devices than it now obtains, but FDA elected not to fully implement the program, despite enthusiasm for the quality of the information it produced and the immediate feedback it gave health-care professionals. The FDA official primarily responsible for the demonstration indicated that it was discontinued because it lacked resources, it generated no significant compliance actions, and it was anticipated that hospital management would be reluctant to participate.

We believe that the results of a recent FDA-sponsored research project and new requirements imposed by the nation's principal hospital accreditation organization could have a significant effect on implementation and outcomes, if the health-experience reporting system or a similar type of system that included hospitals were developed.

In 1984, FDA undertook contracts with the state health departments of Alabama, California, Illinois, Iowa, Massachusetts, Nebraska, and Oklahoma to promote its problem-reporting program through hospital participation. We reviewed reports from these (the Illinois report was not available) and found that the majority of the hospitals indicated they would be interested in participating in an effective problem-reporting program. Effectiveness was characterized as including (1) increased program awareness, (2) timely and useful feedback from reports submitted, (3) a readily accessible data base, (4) relatively inexpensive cost, and (5) some degree of protection from subsequent legal liabilities and punitive actions by the federal government.

The potential costs to FDA would be reduced and the likelihood of hospital cooperation would be increased by the requirement of the commission on accreditation for hospitals that the hospitals that are its members establish a reporting system for problems with devices and appropriate recordkeeping procedures. The existence of such a system would minimize the start-up costs of FDA's system and the concerns of hospital managers.

Limitations to Mandatory Reporting Systems and Systems Based on Probability Sampling

All reporting systems have some inherent characteristics that may reduce the volume and quality of the data they produce. People may not report even to mandatory systems, and without adequate monitoring, an agency may mistakenly believe it is receiving all available data. In our survey, the respondents overwhelmingly cited the seriousness of a problem as a strong or very strong incentive to report it, but we found that hospitals were less likely to report problems involving injury than problems that did not. In spite of this drawback, we believe that mandatory reporting is preferable to voluntary reporting, which may be subject to the same limitation on a larger scale.

Probability sampling techniques are generally adequate for producing reasonably accurate estimates of the extent of adverse events but entail some special areas of concern when applied to postmarketing surveillance for medical devices. The most serious limitation involves the availability of an adequate sampling frame, or the list of relevant elements from which the probability sample is drawn. For example, NEISS draws its sample from a listing of emergency rooms in hospitals in the United States. However, without a listing of the actual population of interest—for example, there is no complete list of injuries associated with the use of consumer products—the Consumer Products Safety Commission samples only emergency rooms where injuries associated with many, but not all, consumer products are treated. Unfortunately, the size of the residual population—that is, persons whose injuries are not treated in emergency rooms—is not known. This kind of population is referred to as a "hidden population."

In the case of medical devices, the population of interest is all problems associated with the use of medical devices, but the ability to generalize from any data we might collect would depend on whether we knew the total number of uses of all medical devices. In addition, some error might be introduced if not all devices were used in all hospitals. Techniques that are available, however, for estimating hidden populations should be useful in these circumstances.

Relatively rare events such as deaths from the use of medical devices may require prohibitively large samples in order to yield a sufficient number of cases for analysis. Several systems we reviewed tried to mitigate this difficulty. NEISS includes only 65 emergency rooms in its national sample, but it is based on continuous reporting of all visits to these rooms. It thus produces a sufficient number of cases to detect most of the relatively rare events. NEISS also aggregates cases over several years. NASS samples accidents within the districts included in its sample, but it oversamples accidents involving serious injuries, in order to provide a sufficient number of cases for analysis. FDA could also oversample rare events of known or suspected significance, such as pacemaker battery failures, and it could aggregate data over several years.

Solutions to Other Problems

The problem of orally transmitted reports could be reduced by requiring written follow-up from those who transmit them and the maintenance of written records from those who receive them. The problem of the flow of information to a number of intermediaries between hospitals and the manufacturers' headquarters, where blockage occurs, could be reduced by requiring these intermediaries to report problems transmitted to them to a central location at the manufacturers' headquarters. Finally, the problem of a general lack of definition as to what constitutes a "complaint" versus routine service and repair could be resolved if FDA developed training and education programs aimed at informing the users of devices as to what constitutes a reportable problem and the manufacturers of devices as to what constitutes a valid complaint. This type of approach to education and information was used by the developers of the Aviation Safety Reporting System.

Summary

During our study period, FDA's principal means of acquiring postmarketing surveillance information on medical devices were the voluntary census of problems reported through USPC and the device experience network. Our review of other federal agencies' hazard-monitoring systems suggests that the underreporting we found throughout the length and breadth of FDA's network might be improved, but the inherent limitations of voluntary reporting systems would still mean that timely, reasonably accurate estimates of the actual nature and extent of device-associated problems could not be produced.

The legal requirement to report under the mandatory reporting systems that other federal agencies use for monitoring hazardous technologies helps minimize most of the factors we found that contribute to underreporting in FDA's voluntary reporting system. In December 1985, FDA implemented a medical-device reporting rule that establishes a mandatory census of device manufacturers, but hospitals are not included in its reporting requirements, even though most problems associated with devices occur in hospitals. According to our survey, hospitals have not exhibited a tendency to voluntarily report to FDA.

FDA's reliance on either the voluntary census reports or the mandatory reports only from manufacturers will not provide it with accurate information about the nature or scope of problems associated with the use of medical devices. A mandatory reporting requirement that includes all the elements in FDA's communications network, based on either a complete census of hospitals and manufacturers or a probability sample of hospitals, would supplement the mandatory reporting by manufacturers and distributors, minimize the problem of underreporting, and provide FDA with the information it needs if it is to have an early warning system and make reasonably accurate estimates of device-associated problems, as expected by congressional oversight committees.

Other elements of FDA's communications system could be strengthened, because merely making reporting mandatory will not solve the problems now inherent in it. Efforts might be made to increase the level of written documentation, to require the intermediaries who receive reports to forward them to a central location, and to educate users, manufacturers, distributors, and others as to what constitutes a reportable problem and a valid complaint.

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Chapter 6

Conclusions, Recommendations, and Agency Comments and Our Response

Medical devices are integral to health care. Their technology has revolutionized the practice of medicine and undoubtedly improved the public health. However, there are risks associated with most technologies, including medical devices. Although devices may be rigorously tested during development and clinical trials, problems cannot always be discerned at this stage. The "push" to have the benefits of a new technology available to the public as soon as possible and the "pull" of withholding it until all possible risks have been determined create a tension for FDA. In this study, we described some of FDA's efforts to resolve this tension, including premarketing review and approval and postmarketing surveillance.

We examined FDA's premarketing review and approval processes in order to understand the setting and need for postmarketing surveillance. An effective postmarketing surveillance system would allow the use of medical devices and the simultaneous detection of problems not identified in the premarketing period. Viewing the postmarketing surveillance system in place during 1984 as a complex communications network that gives FDA early warning about medical-device problems, we looked at the flow of information, the kind of information that is reported, and the responses to reports of problems. We also looked at 15 other systems federal agencies use to monitor other potentially hazardous technologies to see if useful techniques might be transferred to FDA's system for medical devices.

Conclusions

We conclude that the postmarketing surveillance system in place in 1984 does not provide the necessary complement to FDA's premarketing review and approval processes that would give a reasonable assurance that medical devices are safe and effective. Most problems with medical devices in hospitals were unknown to both the manufacturers and FDA. Even when the problems were associated with injuries or had the potential for causing injury, information almost never reached FDA. Since manufacturers are not aware of most problems, we also conclude that the recent regulatory requirement, the medical-device reporting rule of December 1984, that manufacturers report serious problems to FDA will still leave the agency unaware of matters that need attention.

In tracing information flow through the postmarketing surveillance system, we found that almost half the problems known to hospital personnel are never reported outside the hospital. Sixty-four percent of the problems involving injury to patients were not reported. Slightly more than 40 percent of all unreported problems had the potential to cause injury. We conclude that a substantial number of potentially serious problems with medical devices are unknown to FDA.

When we looked at how the communications network operated when hospitals did send out reports of problems, we found that they seldom made reports directly to FDA or through the U.S. Pharmacopeia Convention, an FDA contractor set up to receive reports and pass them along to FDA. Instead, hospital personnel most often notified manufacturers, distributors, or repair services. Very few of these reports were forwarded to FDA. We found that reporting medical-device problems was often linked to repair or replacement. We conclude that the structure and function of the current communications network for postmarketing surveillance does not provide FDA with sufficient postmarketing information to make appropriate postmarketing regulatory decisions.

In our analysis of how hospitals and manufacturers respond to problems with medical devices, we found that actions to repair or replace devices were the most common. From this, we conclude that the main concern was to resolve individual problems rather than to transmit information to FDA. This choice may be reasonable from an individual hospital's point of view, but the early warning function does not fare well.

In reviewing other federal systems used to monitor hazardous technologies, we sought approaches that might correct the underreporting that we believe characterizes FDA's system. We conclude that FDA's current communications network could be strengthened by giving greater emphasis to the early warning function. Our recommendations are aimed at creating a communications network that will better serve FDA's needs for the data that are necessary to recognize and act on patterns of problems.

Recommendations to the Secretary of Health and Human Services

We recommend that the secretary of Health and Human Services (HHS) take the following actions to correct the underreporting of medical-device problems.

1. Independent distributors of medical devices should be required to report information about problems with devices to manufacturers, as manufacturers are required to report to FDA under the medical-device reporting rule.

2. A more effective cooperative relationship should be established with professional health organizations to develop and distribute educational

materials for health-care professionals on FDA's need for early warning information and on how to report medical-device problems.

3. In addition, GAO recommends that FDA explore the possibility of establishing a voluntary, postmarketing surveillance system involving a representative sample of hospitals that would report directly to device manufacturers. This recommendation is made in light of the void of information on problems with medical devices, the potential harm to people that could ensue, and recent developments indicating a more cooperative attitude by hospitals.

Agency Comments and Our Response

The Department of Health and Human Services (HHS) provided general and specific comments on a draft of this report. The comments are printed in appendix XII. In response to these comments, we made specific changes where appropriate in the final draft of the report or addressed them in the appendix. The comments HHS made with regard to our recommendations are discussed below. HHS said that the draft report was generally good and that it provided a valuable baseline analysis of the reporting of adverse events prior to the initiation of the medical-device reporting program. HHS indicated that the report would enhance future evaluations of the effect of the program.

HHS indicated that in drafting the medical-device reporting regulations, FDA considered requiring reports from medical-device distributors. It was decided, however, that the agency should have some experience with manufacturers' reporting before deciding whether to extend the requirements of the regulations to others in the device-distribution chain. HHS stated that experience to date indicates that it may not be necessary to do so. FDA will continue to evaluate the regulations and propose changes should they become necessary.

Our findings show that distributors are a link in the communications network, that they are notified of the occurrence of problems, and that often they do not transmit this information to manufacturers or FDA. We believe our findings support the need to include distributors in the mandatory reporting scheme.

HHS indicated that the intent of our recommendation that hospitals be required to report adverse events is certainly in keeping with FDA's goals but that the specific approach we recommended is problematic. According to HHS, FDA has considered many different approaches to acquiring reports of problems with devices, including a 1980 demonstration in which two hospitals were under contract to collect data on adverse events. The system was never fully implemented for several reasons, including the reluctance of hospitals to participate and the lack of resources to continue and expand the system.

We believe that a cooperative arrangement between hospitals, manufacturers, and FDA, in which a sample of hospitals reported all problems with medical devices directly to the manufacturers, would increase the number of incidents known to manufacturers by (1) increasing the likelihood of reports being made outside hospitals and (2) avoiding the loss of information that occurs when service centers, distributors, and other intermediaries do not forward reports to manufacturers.

As we discussed in chapter 5, we believe that the major factors on which FDA based its decision not to fully implement the health experience reporting system in 1980 should be reevaluated. The results of our study and FDA's own 1984 survey of seven states have shown that hospitals and health-care professionals are concerned about the safety and effectiveness of medical devices and might now be willing to participate in a problem-reporting program. If a representative sample of hospitals would agree to report to manufacturers in a systematic way, similar to the way the hospitals were involved in the 1980 demonstration project, HHS might find that a cost comparison study could favor our approach over the current voluntary census approach of the problem reporting program. This could be so, for example, because a representative sample of hospitals would constitute a smaller sample of the hospitals than are in the current device experience network. To avoid overburdening particular hospitals, procedures could allow the hospitals originally chosen in the sample to be periodically replaced by others.

The position of HHS is that an adequate reporting system might not include receiving reports of all adverse events or problems with devices (most do not lead to adverse events insofar as patients are concerned). The intent of the device-reporting system is to provide FDA with sufficient information to make appropriate postmarketing regulatory decisions, which could range from merely observing the performance of a particular device to requiring that the device be withdrawn from the market. HHS holds that most devices require no postmarketing action by FDA and that designing and implementing such a system, without overburdening hospitals, distributors, manufacturers, or FDA, requires the resolution of some fundamental issues, including the selection and participation of hospitals, professional liability, and system costs.

Our report was not meant to imply that 100-percent reporting is necessary in order for FDA to make appropriate postmarketing regulatory decisions. We believe that the agency is best able to determine the level of reporting that it requires in order to establish the nature and scope of problems related to medical devices. We agree that serious events, such as those described in the medical-devices reporting rule, are the most important ones to report. The rule requires that manufacturers and importers of medical devices report to FDA when they become aware of serious problems associated with their devices, and the reporting of serious, adverse events may have increased as a result of the rule. However, we found in our study that the most serious events were less likely to be reported outside the hospitals. For example, among the unreported incidents uncovered in our study was one that involved the death of a patient. This gap in the flow of information raises serious questions about the nature and scope of problems that can be identified by the regulation, and we draw the attention of HHS analysts to the need to rethink this issue.

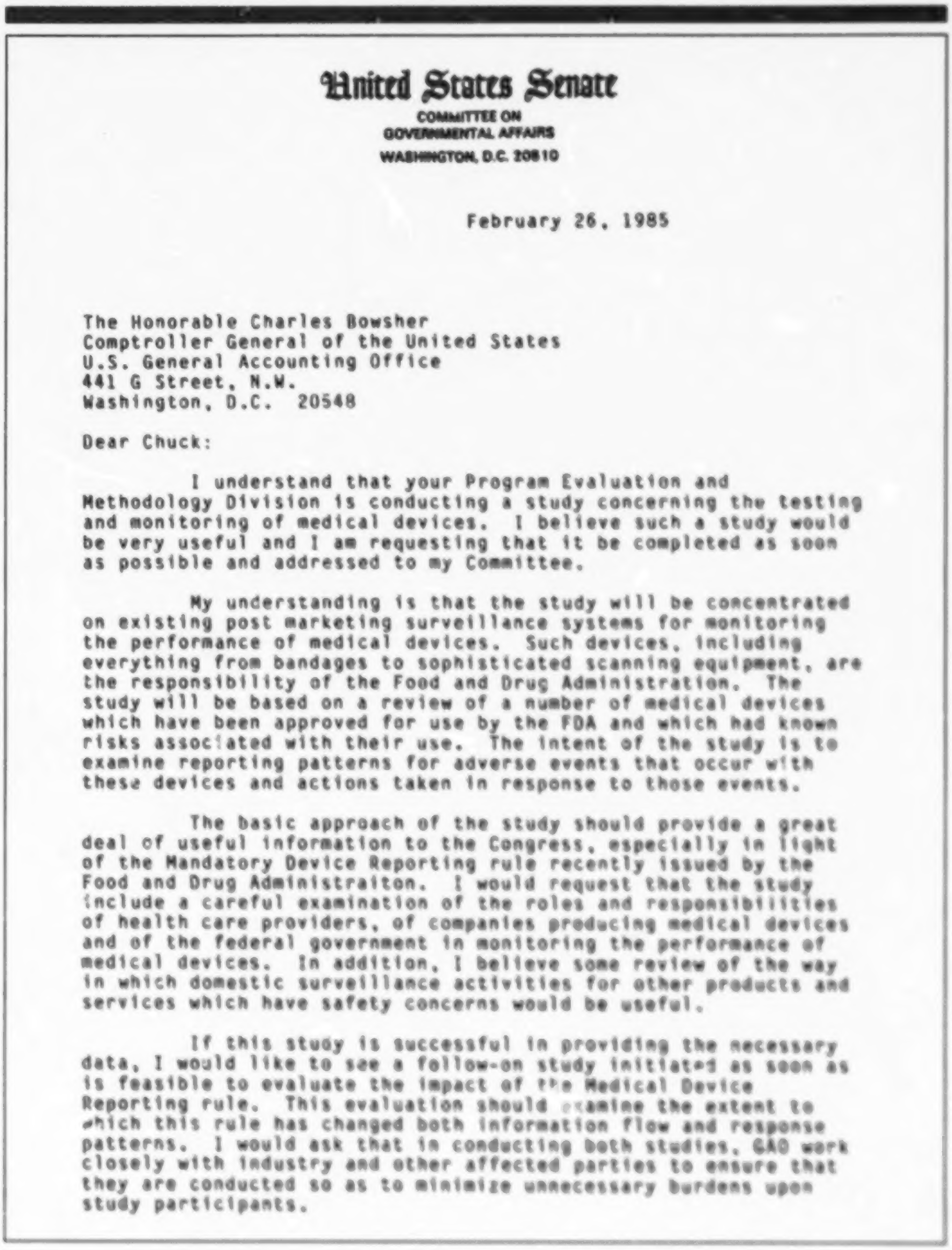
We concur with HHS that the issues it poses are among those that should be addressed, through an empirical study, before implementing an enhanced reporting system. This is precisely why we recommend that HHS explore the possibility of changing FDA's system for postmarketing surveillance, so that it will include the systematic but voluntary reporting of problems with devices, by a representative sample of hospitals, directly to the device manufacturers. We recognize that there are obstacles to be overcome in changing the postmarketing surveillance system, and we believe that FDA's producing a strong study would go a long way toward doing this. We note also that many attitudes in the hospital community have changed since FDA's 1980 experience: we were told when we started this study that we would not get much help from hospitals, but we found exemplary cooperation from them. Indeed, they are not only as much concerned about these issues as anyone else but probably more so. The concern indicated in their 81-percent response rate to our study reflects the change in attitudes since FDA's 1980 demonstration.

In commenting on our third recommendation, HHS stated that FDA has a well-established, cooperative program with medical-device manufacturers and the health professionals who use devices that is based upon their belief in the effectiveness of educational efforts for solving problems. HHS added that FDA has undertaken extensive and costly efforts to publicize the existence of the program and its need for information. HHS indicated that the agency was dismayed that our report revealed a general lack of awareness of the program among health-care professionals. HHS said that FDA is now looking for other ways to reach health-care professionals with this information and to encourage their participation, bearing in mind the agency's limited resources for pursuing educational programs. According to HHS, since this problem has just come to its attention, a specific course of action could not yet be taken.

We recognize that FDA has undertaken extensive and costly efforts to publicize the problem-reporting program and that it needs information. However, an examination is also needed of the implementation of FDA's efforts, in order to determine why awareness of the program is so low among health-care professionals. Any postmarketing surveillance system must depend upon hospital personnel to initiate reports. We believe that steps should be taken to increase the likelihood that adverse events will be reported when they occur. Given the concern that hospital personnel already have about the use of medical devices, we believe that simply increasing their awareness of FDA's need for information and how to report problems will improve the information available to FDA.

Appendix I

Request Letter



United States Senate
COMMITTEE ON
GOVERNMENTAL AFFAIRS
WASHINGTON, D.C. 20510

February 26, 1985

The Honorable Charles Bowsher
Comptroller General of the United States
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

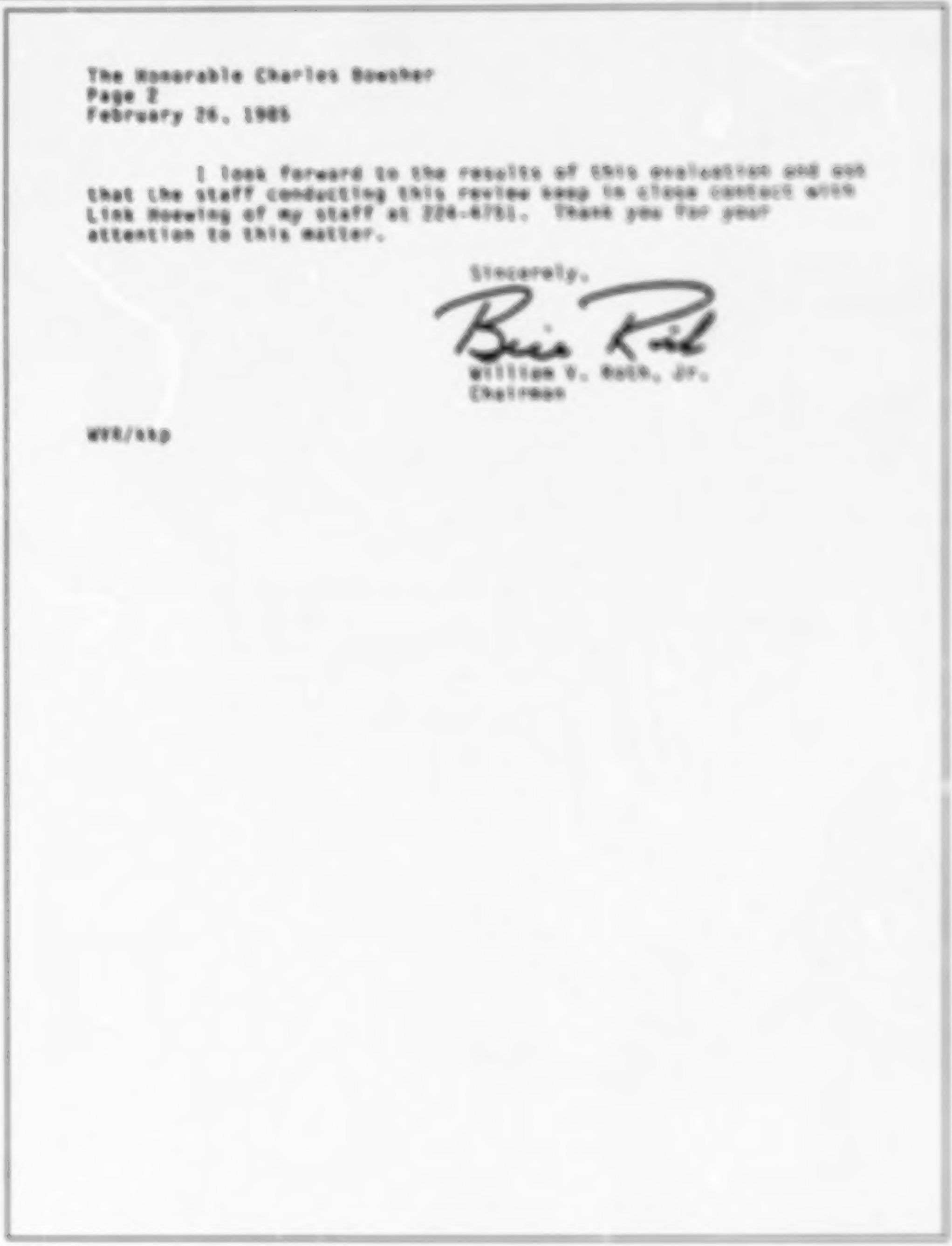
Dear Chuck:

I understand that your Program Evaluation and Methodology Division is conducting a study concerning the testing and monitoring of medical devices. I believe such a study would be very useful and I am requesting that it be completed as soon as possible and addressed to my Committee.

My understanding is that the study will be concentrated on existing post marketing surveillance systems for monitoring the performance of medical devices. Such devices, including everything from bandages to sophisticated scanning equipment, are the responsibility of the Food and Drug Administration. The study will be based on a review of a number of medical devices which have been approved for use by the FDA and which had known risks associated with their use. The intent of the study is to examine reporting patterns for adverse events that occur with these devices and actions taken in response to those events.

The basic approach of the study should provide a great deal of useful information to the Congress, especially in light of the Mandatory Device Reporting rule recently issued by the Food and Drug Administraiton. I would request that the study include a careful examination of the roles and responsibilities of health care providers, of companies producing medical devices and of the federal government in monitoring the performance of medical devices. In addition, I believe some review of the way in which domestic surveillance activities for other products and services which have safety concerns would be useful.

If this study is successful in providing the necessary data, I would like to see a follow-on study initiated as soon as is feasible to evaluate the impact of the Medical Device Reporting rule. This evaluation should examine the extent to which this rule has changed both information flow and response patterns. I would ask that in conducting both studies, GAO work closely with industry and other affected parties to ensure that they are conducted so as to minimize unnecessary burdens upon study participants.



The Honorable Charles Bowsher
Page 2
February 26, 1985

I look forward to the results of this evaluation and ask that the staff conducting this review keep in close contact with Link Hoewing of my staff at 224-4751. Thank you for your attention to this matter.

Sincerely,

Bill Roth

William V. Roth, Jr.
Chairman

WVR/skp

Appendix II

The Members of Our Device-Selection Panel

Dr. Carl Bruch
Vice President of Quality and Regulatory Affairs
Skyland Scientific Services, Inc.
Belgrade, Montana

Dr. Howard G. Clark, III
Director of the Center for Biochemical Engineering
Duke University
Durham, North Carolina

Mr. Ken Henkelman
President of Medical Equipment
San Bruno, California

Dr. William Hyman
Professor of Biochemical Engineering
Texas A&M University
College Station, Texas

Mr. Robert Mosenkis
Certified Clinical Engineer
Emergency Care Research Institute
Plymouth Meeting, Pennsylvania

Dr. Henry Piehler
Professor of Metallurgical Engineering and Material Science
Department of Engineering and Public Policy
Carnegie Institute of Technology
Pittsburgh, Pennsylvania

Mr. Marvin Shepherd
Engineer
Medical Center of the University of California
San Francisco, California

Appendix III

The Members of Our Technical Advisory Review Board

Dr. William C. Beck
President Emeritus
Donald Gutherie Foundation for Medical Research
Sayre, Pennsylvania

Dr. Edward R. Duffie
Beckton Dickinson and Company
Paramus, New Jersey

Dr. Manuel Dujovny
Henry Ford Hospital
Detroit, Michigan

Mr. Allen Greenberg
Public Citizen Health Research Group
Washington, D.C.

Ms. Mary Ann Kelly
Division of Management and Technology
American Hospital Association
Chicago, Illinois

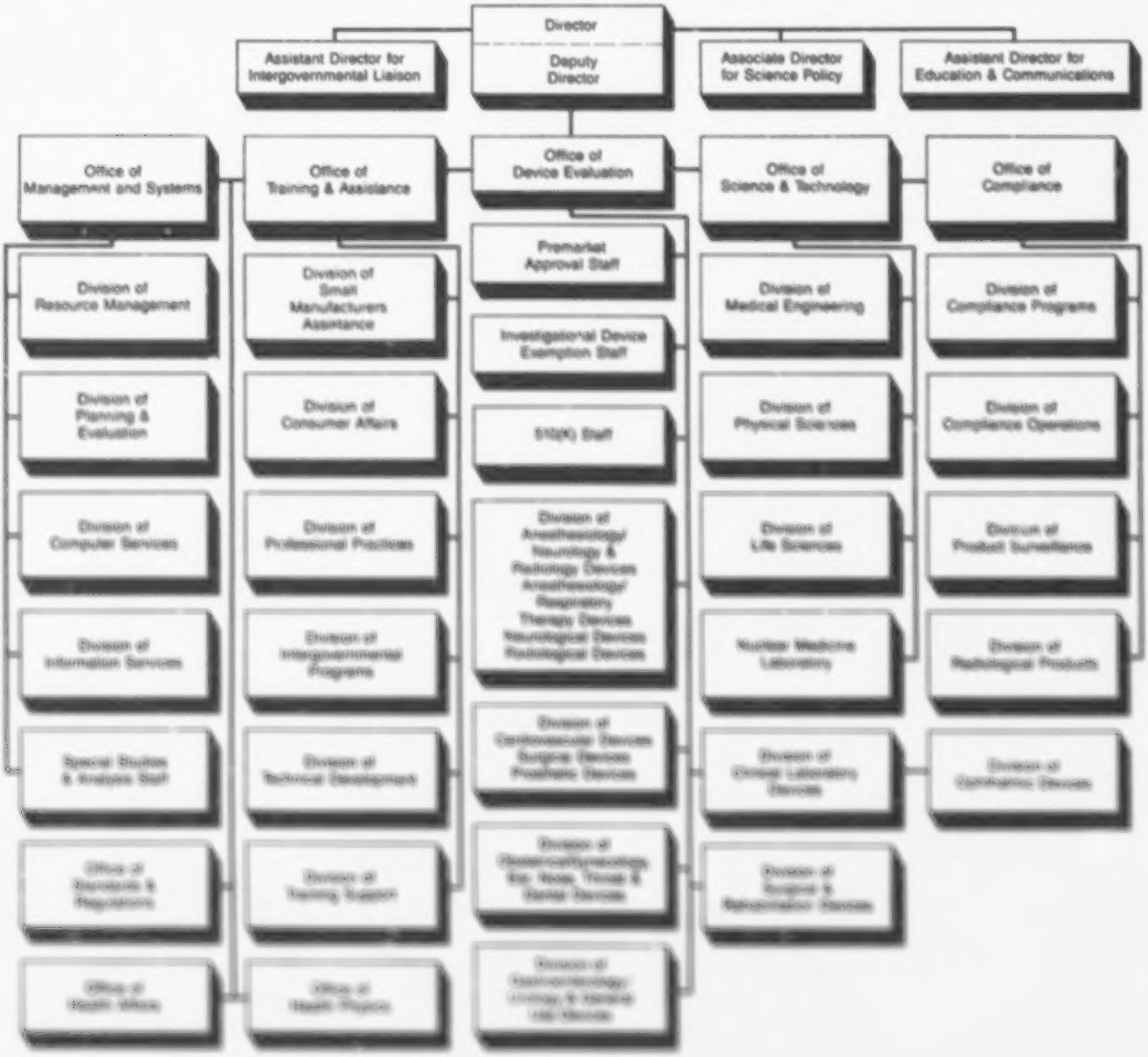
Dr. Nir Kossovsky
The New York Hospital
Cornell Medical Center
New York, New York

Dr. Ram Kossowsky
Westinghouse Research and Development Center
Pittsburgh, Pennsylvania

Mr. John Kuchta
Vice President of Kendall Company
Boston, Massachusetts

Dr. William T. McGivney
Acting Director of Technology Assessment
American Medical Association
Chicago, Illinois

Organizational Flowchart of the FDA Center for Devices and Radiological Health


Director
Deputy Director
Assistant Director for Intergovernmental Liaison
Associate Director for Science Policy
Assistant Director for Education & Communications
Office of Management and Systems
Office of Training & Assistance
Office of Device Evaluation
Office of Science & Technology
Office of Compliance
Division of Resource Management
Division of Planning & Evaluation
Division of Computer Services
Division of Information Services
Special Studies & Analysis Staff
Office of Standards & Regulations
Office of Health Affairs
Division of Small Manufacturers Assistance
Division of Consumer Affairs
Division of Professional Practices
Division of Intergovernmental Programs
Division of Technical Development
Division of Training Support
Office of Health Physics
Premarket Approval Staff
Investigational Device Exemption Staff
510(K) Staff
Division of Anesthesiology/ Neurology & Radiology Devices Anesthesiology/ Respiratory Therapy Devices Neurological Devices Radiological Devices
Division of Cardiovascular Devices Surgical Devices Prosthetic Devices
Division of Obstetrics/Gynecology, Ear, Nose, Throat & Dental Devices
Division of Gastroenterology/ Urology & General Use Devices
Division of Medical Engineering
Division of Physical Sciences
Division of Life Sciences
Nuclear Medicine Laboratory
Division of Clinical Laboratory Devices
Division of Surgical & Rehabilitation Devices
Division of Compliance Programs
Division of Compliance Operations
Division of Product Surveillance
Division of Radiological Products
Division of Ophthalmic Devices

Source: [illegible]

Our Procedures for Selecting the Samples of Medical Devices, Hospitals, and Respondents

The Sample of Medical Devices

We chose our sampling procedure for medical devices primarily to allow conclusions about the flow of information in the communications network that supports the postmarketing surveillance of medical devices. The procedure was not intended to be the basis for conclusions about the frequency of problems with medical devices, either overall or for particular groups of devices.

The literature and our discussions with experts on medical devices suggested that most devices have few problems associated with them. To avoid collecting data on a few incidents for many products, we decided to focus the study on a select group of devices. Since thousands of medical devices are in use and our resources were limited, we decided to restrict our study to 10 devices. We opted for a judgmental sample on which there was general agreement that information should exist on problems associated with their use. A sample of this type constitutes what might best be described as an "extreme case strategy," in that it focused on devices the experts believed were sufficiently problematic to have led to reports of problems and continuing information transmissions within the postmarketing surveillance systems.

The strategy permitted us to estimate the extent to which information about problems was passed through the communications network—the proportion of device problems reported outside hospitals, for example. We believe that our estimates indicate the highest transmission rates in the network. The estimates for a different set of devices might be lower but they would not be likely to be higher. Similarly, we believe that the actual transmission rates for all device problems in 1984, if it were possible to know such numbers, would be smaller than our estimates.

The panel of experts listed in appendix II each submitted a list of devices that met the following criteria:

1. the use of the device has caused or is likely to cause serious injury or death or to affect large numbers of patients,

2. the nature and magnitude of the risk or problems became apparent after marketing,

3. the device is used in hospitals, and

4. the risks were recently recognized (preferably in a device or model of devices FDA has reviewed or approved since 1976).

After the lists were submitted, our panel was convened for a 1-day session to reach consensus on the devices that would be suitably included in the sample. The session yielded a list of 33 devices, from which we selected the final sample of 10.

Because we wanted to cover the widest practical range of devices, we also wanted the final sample to include examples from each of five categories of devices developed by the Emergency Care Research Institute for FDA.[1] In addition, we wanted to account for the many different types of devices, many of which have different safety implications. For example, a long-term implant such as a pacemaker might fail many years after implantation but asphyxiation from a malfunctioning tracheal tube is immediate. Failures associated with diagnostic devices cause harm indirectly by providing false positive or false negative diagnoses, while an overheated radiant warmer has a direct link to a patient's harm. A detailed description of the 10 devices we selected, including their use, users, and potential safety problems, is in appendix VI. Table V.1 shows the final sample of devices by category.

Table V.1: Ten Sampled Devices by Category and FDA's Risk Classification

Category	Device	Risk class
Long-term implant	Replacement heart valve	III
	Intraocular lens	III
Short-term implant	Hemodialysis system and accessories	II
	Tracheal tube and inflatable tracheal tube cuff	II
Drug-dispensing device	Infusion pump and controller	II
	Anesthesia gas machine	II
External device	Infant radiant warmer	III
	Electrosurgical cutting and coagulation device	II
	Pneumatic tourniquet	II
Diagnostic and monitoring device	Arrhythmia detector and alarm	III

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[1] See Emergency Care Research Institute, National Device Experience Monitoring System (Plymouth Meeting, Pa.: June 1975).

The Hospital Samples and Respondents

We selected 10 stratified random samples of hospitals, one for each of the 10 sample devices, from the nationwide population of 4,603 community hospitals with 50 or more beds.[2] Community hospitals include all nonfederal, short-term, general, and other special hospitals. They represent 65 percent of all hospitals in the United States and 76 percent of all acute-care community facilities. We excluded long-term care facilities—that is, hospitals specializing in tuberculosis and other respiratory diseases, chronic disease, psychiatric problems, alcoholism, and chemical dependency—as well as hospitals with fewer than 50 beds, because of the limited number of devices routinely used in these facilities.

The sampling frame of hospitals was stratified according to six bed-size categories, and each hospital we selected was randomly assigned to 1 of the 10 devices. We sampled approximately 200 hospitals per device, except that we included an additional 38 hospitals for heart valves, oversampling because of the relatively small number of hospitals that perform open heart surgery. We selected hospitals randomly from each of the four smallest bed-size strata and all the hospitals in strata 5 and 6. (See table V.2.)

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[2] See American Hospital Association, Annual Survey of Hospitals (Chicago, Ill.: 1983).

Table V.2: The Number of Hospitals in the Original and Final Samples by Device and Hospital Bed Size

Device	50-99 beds	100-199 beds	200-299 beds
Replacement heart valve	28	45	33
Intraocular lens	171	170	66
Hemodialysis system and accessories	44	73	81
Tracheal tube and inflatable tracheal tube cu	166	160	74
Anesthesia machine	168	182	81
Infusion pump and controller	184	185	79
Electrosurgical cutting and coagulation devic	166	154	96
Infant radiant warmer	154	122	71
Pneumatic tourniquet	167	139	72
Arrhythmia detector and alarm	177	167	75
Total hospitals	**1,425**	**1,397**	**728**

Our preliminary research had shown that hospital positions, titles, and responsibilities vary from hospital to hospital. Likewise, the persons who hold the positions differ in their knowledge about specific devices. Therefore, we directed the screening questionnaire, shown in appendix VII, to five types of hospital personnel, in the hope of contacting the most knowledgeable person in each hospital about the devices. These included individuals responsible for (1) purchasing devices, (2) repairing and servicing them, and (3) using them in clinical procedures and, for problems that involved injury or death, (4) hospital risk managers and (5) quality-assurance officers, who are usually responsible for investigating such incidents. We sent five copies of the questionnaire to the hospital administrators, who were asked to distribute them to the persons occupying these positions in their hospitals. We assured them of the confidentiality of all information they would provide.

The screening questionnaire asked "During the 1984 calendar year, did your hospital have any problems involving [one device selected from our sample of 10]?" and "When did the most significant problem occur from a safety perspective and is this the actual or estimated date?" Each respondent who indicated a device-associated problem during 1984 was then sent the full hospital questionnaire. Hospitals that identified a

Original sample				Final sample						
300-399 beds	400-499 beds	500+ beds	Total original hospitals	50-99 beds	100-199 beds	200-299 beds	300-399 beds	400-499 beds	500+ beds	Total final hospitals
32	40	60	238	28	45	33	32	40	60	238
37	21	30	495	57	57	22	13	21	30	200
58	38	53	347	19	31	34	25	38	53	200
49	32	35	516	48	47	22	16	32	35	200
44	24	21	520	55	59	26	15	24	21	200
42	22	35	547	54	54	23	12	22	35	200
46	22	20	504	56	52	33	16	22	20	199
39	30	31	447	54	44	26	15	30	31	200
49	21	29	477	59	49	25	18	21	29	201
44	24	25	512	58	54	24	15	24	25	200
440	**274**	**339**	**4,603**	**488**	**492**	**268**	**177**	**274**	**339**	**2,038**

problem associated with a medical device on the screening questionnaire received one or more detailed questionnaires in which we asked for further information on that problem. From some hospitals, we received separate screening questionnaires from persons occupying different positions within the hospital, all identifying a single problem. We sent multiple detailed questionnaires to these hospitals, asking for information on this problem. In order to avoid duplication in our analysis of the detailed questionnaires (that is, to avoid reporting on the same problem more than once), we applied a duplication code to each instrument; this allowed us to select only one instrument per problem for our analysis.

We applied the duplication code after we examined all the detailed questionnaires that we received on a single specific problem. We made every attempt to include the "most fully completed" questionnaires in the analysis, or those missing the least data and identifying the greatest number of contacts outside the hospitals.

The analysis of data from the screening survey showed that awareness of problems associated with devices varied by the position of respondents within a hospital. Overall, the repair and service technicians and the primary users of a device were the most likely to know about a problem with it. About 29 percent of all the repair and service technicians who responded indicated that a problem occurred with a medical device. Approximately 23 percent of all primary users of a device who responded indicated a problem. About 15 percent of the quality-assurance officers and 14 percent each of purchasing agents and risk managers identified the occurrence of a problem associated with a medical device in their hospitals.

Description of the 10 Medical Devices in Our Sample

Long-Term Implanted Devices

The primary users of long-term implanted devices are physicians. We selected two devices: the replacement heart valve and the intraocullar lens. Both are class III devices.

Replacement Heart Valve

A replacement heart valve is a generic device intended to perform the function of any of the heart's natural valves and includes valves constructed of prosthetic or biological materials (such as porcine valves) or a combination of these. There are two main debilitating or fatal risks to health. One is thromboembolism, stemming from an incompatibility between the blood and the materials used in the device or inadequate surface finish and cleanliness. The other may be excessive regurgitation, excessive hemolysis, improper hemodynamic operation, excessive obstruction, or valve degeneration, caused by poor valve design, among other things.

Intraocular Lens

The intraocular lens is intended to replace the natural lens of the human eye after surgical removal, generally as a result of a cataract. Implanted lenses entail various types of attachments that are usually manufactured from polymeric materials. There are several risks to health. Serious injuries, including eye loss, have been reported after implantation. Improper sterilization has resulted in cases of eye infection. Surgical complications may include transient glaucoma and damage to other parts of the eye. Dislocation, or the forward or backward displacement of the lens, is a possible complication whose incidence varies and appears to be related to lens design. Although a dislocated lens can usually be repositioned by an ophthalmologist without elaborate surgical procedures, it may result in blurred vision, discomfort, glaucoma, or endothelial corneal dystrophy.

Short-Term Implanted Devices

The primary users of short-term implanted devices are physicians, nurses, and technicians. The two devices we selected were the hemodialysis system and accessories and the tracheal tube and inflatable tracheal tube cuff. Both are class II devices.

Hemodialysis System and Accessories

A hemodialysis system and its accessories constitute an artificial kidney system for the treatment of patients with renal failure or toxemic conditions. FDA has placed it in class II, except for certain accessories, which include unpowered dialysis chairs, hemodialysis start-stop trays, dialyzer holder sets, and dialysis tie guns and ties. The FDA advisory panel recommends that these be placed in class I. There are two major types of systems—peritoneal and extracorporeal. We focused primarily on the extracorporeal blood system that includes a conventional dialyzer, a dialysate delivery system, and accessories.

Blood from the patient flows through the tubing of the extracorporeal blood system to the blood compartment of the dialyzer and then returns through further tubing to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane, blood on one side and the dialysate on the other. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate that circulates through this compartment.

The extracorporeal blood system consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms. These keep the blood moving safely from the blood access device and accessories to the blood compartment of the dialyzer and back to the patient. The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane, which has a permeability to water low enough not to require an ultrafiltration controller to prevent excessive loss of water from the patient's blood. The conventional dialyzer does not include hemodialyzers with disposable inserts (Kiil type) or dialyzers of high permeability.

The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulate it through the dialysate compartment. Alarms indicate abnormal conditions. The term "dialysate delivery system" also includes the sorbent regenerated dialysate delivery system. Dialysate delivery systems are used not only with extracorporeal but also with peritoneal and high-permeability hemodialysis systems.

The FDA advisory panel previously identified this type of device and its parts as the dialysis transducer protector; blood tubing set with or without antiregurgitation valve; dialysis blood filter; Y adapter; infusion T blood and dialysate tubing connectors; extraluminal blood pump; blood pump insert; blood level and blood leak detectors; automatic blood tubing clamp and line clamp; air or foam and air bubble detectors; pillow pressure alarm single-needle dialysis set (alternating flow, controller, and tubing only); hollow fiber capillary flow and parallel flow dialyzers; single and twin coil dialyzers; central multiple patient, recirculating, single-pass, recirculating single-pass, and single patient dialysate delivery systems; negative pressure dialysis control system; dialysate proportioning subsystem; water manometer; holding tank; coil cannister; remote and nonremote conductivity meters; dialysate standard conductivity test solution; dialysate level detector, flow meter, and tubing; and dialysis temperature monitor.

Hemodialysis systems entail many risks to health. Improper design, construction, or malfunction may result in electrical injury to the patient or the operator. Defects in design and construction that prevent adequate cleaning or sterilization, or defects in packaging or processing, may allow pathogenic organisms to contaminate a sterile system and cause an infection in the patient. The patient may have an adverse tissue reaction if the materials used in the construction of the device are not biocompatible, degrade by interaction with body tissue or fluids, or contain residual matter. Toxic substances may be leached from or transmitted by the device, causing the patient to have a pyrogenic reaction, or a sudden fever with collapse and chills. Repeated exposure to substances leached from materials that contact the blood or dialysate may lead to an accumulation of these substances in the patient's body and cause a toxic effect. An incorrect composition of the dialysate may result in electrolyte imbalance in the patient's blood and lead to cardiac disorders, blood cell damage, or muscle cramps. An abnormally high or uncontrolled ultrafiltration rate may result in hypotension, hypovolemic shock, or both, and a dialysis chair that does not allow for easy and rapid repositioning of the patient during a hypotensive episode may delay the treatment of hypovolemic shock.

Further risks include the loss of protein from the blood from inappropriately high membrane permeability. The inability of an air foam or bubble detector to sense small air bubbles or the presence of foam may allow a potentially fatal embolus to enter the patient's bloodstream. Malfunctions, inappropriately low membrane permeability, inadequate blood flow, or leakage in the dialysate delivery system may cause inadequate removal of toxic substances from the patient's blood. The patient's blood may be lost from manufacturing or structural defects that puncture the dialyzer membrane and cause it to fall from its holder or that sever blood lines or dialysate tubing or prevent the sensors from detecting blood leakage into the dialysate. The materials used in the construction of the device, improper design of the blood pump, or excessive dialysate temperature may result in hemolysis, thromboembolic complications, or other damage to the patient's blood. Inadequate design of the dialysis chair or covering materials that prevent adequate cleaning between patients may result in microbial crosscontamination.

Tracheal Tube and Inflatable Tracheal Tube Cuff

A tracheal tube inserted into a patient's trachea through the nose or mouth is used to maintain an open airway. The inflatable tracheal tube cuff provides an airtight seal between the tube and the trachea. Several risks to health are possible. If the device is not sterile, infection may result. If the materials of the device are not flexible, or if the cuff is not of the proper size, shape, or length, the laryngeal or tracheal walls may be damaged while the tube is being inserted. If the cuff comes off the tracheal tube, it may become lodged in the airway and obstruct airflow, or if the cuff fails to inflate, the patient may not receive adequate ventilation through the tracheal tube, and the upper airway will not be adequately protected. If the cuff is composed of a material that is not compatible with the tissues of the trachea, an allergic tissue reaction may occur.

Drug-Dispensing Devices

The primary users of drug-dispensing devices are anesthesiologists, physicians, technicians, and nurses. We selected two class II devices, the infusion pump and controller and the anesthesia gas machine.

Infusion Pump and Controller

An infusion pump is a piston, roller, or peristaltic pump, powered electrically or mechanically, that pumps fluids into a patient in a controlled manner. It may include a means of detecting air in or a blockage of the infusion line and activate an alarm. The advisory panels identified the following risks to health. Because the device is frequently used in close proximity to conductive beds and catheters to the heart, a leakage of electrical current may cause electrical microshock or macroshock or arrhythmia. Failing to deliver a drug at the prescribed flow rate may lead to overdosage or underdosage. If the pump is unable to detect when the reservoir is empty or if a connection or component leaks, air may be infused into the patient. Overpressurization may cause extravasation in the patient, or an overflow of fluid into surrounding tissues. If the alarm is overly sensitive to the environment, it may be activated for a reason other than the one for which it was designed; a consequent high rate of false positive alarms may lead some personnel to disregard the alarm as a signal of the patient's distress.

Anesthesia Gas Machine

An anesthesia gas machine is used to administer, continuously or intermittently, a general inhalation anesthetic or analgesic agent to a patient and to maintain the patient's ventilation. The device may include a gas flow meter, vaporizer, ventilator, breathing circuit with bag, and emergency gas supply. The FDA advisory panels noted the following risks to health. Incorrect calibration may lead to the delivery of an incorrect gas mixture. Poor design or malfunction may mean leaks that cause the patient to receive less than the appropriate gas volume. Mechanical failure obstructing the air pathway may result in the patient's receiving inadequate ventilation. Mechanical failure resulting in overpressurization of the patient's pulmonary system may lead to overdistension of lung tissue (pneumothorax). Fire and explosion from flammable or explosive anesthetic agents may result in severe injury to the patient. Mechanical failure of the device's valves and flow meters may cause brain damage, cardiac arrest, or death.

External Devices

The primary users of external devices are physicians and nurses. We selected three: the infant radiant warmer, a class III device, and the electrosurgical cutting and coagulation device and accessories and the pneumatic tourniquet, both class II devices.

Infant Radiant Warmer

An infant radiant warmer is a device consisting of an infrared heating element that is placed over an infant to maintain the infant's body temperature. It may be placed over a pediatric hospital bed or built into the bed as a complete unit (neonatal open bed with radiant heat). It may contain a temperature monitoring sensor, a heat output control mechanism, and an alarm to alert operators of the device's failure.

There are at least four risks to health. Improper design and construction or malfunction may result in electrical shock. A device constructed of material that absorbs radiant heat may burn hospital staff. If the device is not designed for stability, it may fall and injure the infant, or if the energy output is too high, the device may burn the infant. Radiant heat causes vessel dilation, which in turn may produce insensible water loss in the infant. If the temperature sensor or probe becomes dislodged or is improperly placed, hyperthermia or hypothermia in the infant may result. The literature also describes frequent mechanical failures, such as failure of the alarm and detachment of parts. The long-term effects of infrared radiation on the infant's eyes are unknown.

Electrosurgical Cutting and Coagulation Device and Accessories

Electrosurgical cutting and coagulation devices use high-frequency electrical current for the surgical removal of tissue and the control of bleeding. They include special electrosurgical devices such as those for endoscopic electrocautery, gastroenterology, and urology procedures and bipolar and unipolar endoscopic coagulator cutters and accessories used in female sterilization.

There are several risks to health. Improper electrical design may result in inadequate cutting or coagulation. Inadequate design of electrode return plates and conductive gels may cause burns in the patient. Materials used in the electrodes or electrode gel may cause an allergic or toxic reaction. Used in the presence of flammable skin preparations or surgical drapes, the device may cause a fire or explode. An explosion may result from the ignition of accumulated bowel or bladder gases during surgery. Cataracts may be formed when the device is used near the eye. It may interfere electronically with pacemakers. Excess leakage of electrical current from the device may result in cardiac arrhythmias. Improper electromagnetic shielding, resulting in radiofrequency interference to or from other equipment, may lead to erroneous readings, leading in turn to hazardous or inappropriate therapy. The device may produce radiofrequency irradiation with adverse biological effects.

Pneumatic Tourniquet

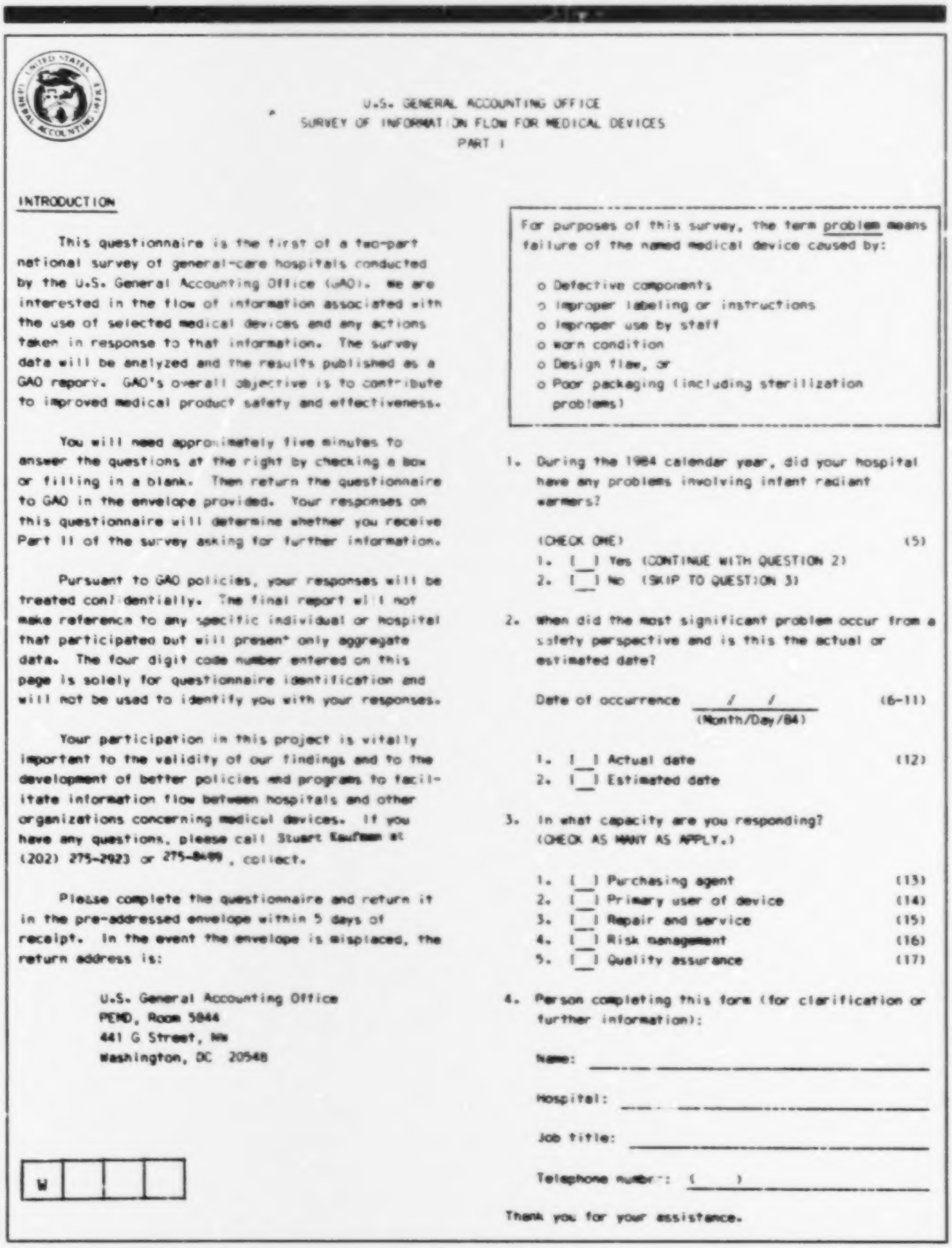
A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit and an inflatable cuff that is intended to be wrapped around a patient's arm or leg and inflated, in order to reduce circulation in the limb. Unstable pressure settings may destroy tissue if excessive pressure is applied to the patient's body. In addition, the accurate functioning of this device is critical in some surgical procedures: serious injuries and deaths have been reported from its failure.

Diagnostic and Monitoring Devices

The primary users of diagnostic and monitoring devices are laboratory technicians, nurses, physicians, and technologists. We selected one class III device, the arrhythmia detector and alarm.

An arrhythmia detector and alarm is a system that monitors the electrocardiogram, producing a visible or audible signal or alarm at the occurrence of an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation. Excessive leakage of electrical current may disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Inadequate design of the processing circuitry or program can produce inaccurate diagnostic data that may lead the physician to prescribe treatment that risks the patient's health unnecessarily.

The Screening Survey



U.S. GENERAL ACCOUNTING OFFICE
SURVEY OF INFORMATION FLOW FOR MEDICAL DEVICES
PART I

INTRODUCTION

This questionnaire is the first of a two-part national survey of general-care hospitals conducted by the U.S. General Accounting Office (GAO). We are interested in the flow of information associated with the use of selected medical devices and any actions taken in response to that information. The survey data will be analyzed and the results published as a GAO report. GAO's overall objective is to contribute to improved medical product safety and effectiveness.

You will need approximately five minutes to answer the questions at the right by checking a box or filling in a blank. Then return the questionnaire to GAO in the envelope provided. Your responses on this questionnaire will determine whether you receive Part II of the survey asking for further information.

Pursuant to GAO policies, your responses will be treated confidentially. The final report will not make reference to any specific individual or hospital that participated but will present only aggregate data. The four digit code number entered on this page is solely for questionnaire identification and will not be used to identify you with your responses.

Your participation in this project is vitally important to the validity of our findings and to the development of better policies and programs to facilitate information flow between hospitals and other organizations concerning medical devices. If you have any questions, please call Stuart Kaufman at (202) 275-2923 or 275-8499, collect.

Please complete the questionnaire and return it in the pre-addressed envelope within 5 days of receipt. In the event the envelope is misplaced, the return address is:

U.S. General Accounting Office
PEMD, Room 5844
441 G Street, NW
Washington, DC 20548

W			

For purposes of this survey, the term problem means failure of the named medical device caused by:

- o Defective components
- o Improper labeling or instructions
- o Improper use by staff
- o Worn condition
- o Design flaw, or
- o Poor packaging (including sterilization problems)

1. During the 1984 calendar year, did your hospital have any problems involving infant radiant warmers?

(CHECK ONE) (5)
1. ☐ Yes (CONTINUE WITH QUESTION 2)
2. ☐ No (SKIP TO QUESTION 3)

2. When did the most significant problem occur from a safety perspective and is this the actual or estimated date?

Date of occurrence ___/___/___ (6-11)
(Month/Day/84)

1. ☐ Actual date (12)
2. ☐ Estimated date

3. In what capacity are you responding?
(CHECK AS MANY AS APPLY.)

1. ☐ Purchasing agent (13)
2. ☐ Primary user of device (14)
3. ☐ Repair and service (15)
4. ☐ Risk management (16)
5. ☐ Quality assurance (17)

4. Person completing this form (for clarification or further information):

Name: ______________________

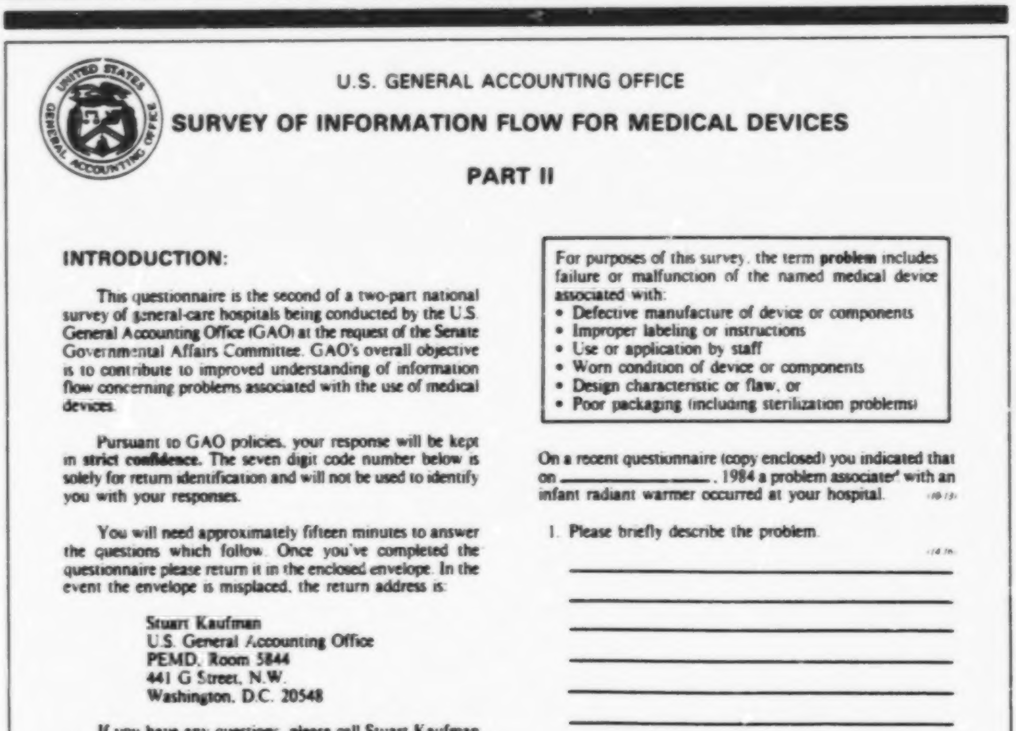
Hospital: ______________________

Job title: ______________________

Telephone number: (   ) ______________________

Thank you for your assistance.

The Full Hospital Survey



U.S. GENERAL ACCOUNTING OFFICE

SURVEY OF INFORMATION FLOW FOR MEDICAL DEVICES

PART II

INTRODUCTION:

This questionnaire is the second of a two-part national survey of general-care hospitals being conducted by the U.S. General Accounting Office (GAO) at the request of the Senate Governmental Affairs Committee. GAO's overall objective is to contribute to improved understanding of information flow concerning problems associated with the use of medical devices.

Pursuant to GAO policies, your response will be kept in **strict confidence.** The seven digit code number below is solely for return identification and will not be used to identify you with your responses.

You will need approximately fifteen minutes to answer the questions which follow. Once you've completed the questionnaire please return it in the enclosed envelope. In the event the envelope is misplaced, the return address is:

Stuart Kaufman
U.S. General Accounting Office
PEMD, Room 5844
441 G Street, N.W.
Washington, D.C. 20548

If you have any questions, please call Stuart Kaufman at (202) 275-2923 or 275-8499, collect.

Your participation in this project is vitally important to the validity of our findings. If you would like a copy of our report, please check the following box. 1 ☐ (9)

Thank you for your cooperation and assistance.

W	☐	☐	☐	☐	☐	1

For purposes of this survey, the term **problem** includes failure or malfunction of the named medical device associated with:

- Defective manufacture of device or components
- Improper labeling or instructions
- Use or application by staff
- Worn condition of device or components
- Design characteristic or flaw, or
- Poor packaging (including sterilization problems)

On a recent questionnaire (copy enclosed) you indicated that on ______________, 1984 a problem associated with an infant radiant warmer occurred at your hospital. (10-13)

1. Please briefly describe the problem. (14-16)

____
____
____
____
____
____

2. Please enter the manufacturer, distributor, and model number of the specific unit associated with the problem.

a. Manufacturer ______________________ (17-19)
b. Distributor ______________________ (20-22)
c. Model Number ______________________ (23)

3. Which of the following apply to the device or component associated with the problem you reported? *(Check all that apply.)*

1. ☐ Covered by manufacturer's warranty (24)
2. ☐ Covered by manufacturer's service contract (25)
3. ☐ Covered by other service contract *(Specify.)* (26)
____
4. ☐ Covered by exchange program (Formal or informal agreement with vendor to accept return of or replace unsatisfactory merchandise) (27)
5. ☐ None (28)
6. ☐ Do not know (29)

—1—

4. In what department of the hospital was the problem first discovered?

______________________________ (30-31)
Department Name

5. What is the position of the individual who first discovered the problem? *(Check one.)* (32)

1. ☐ Biomedical engineer/technician
2. ☐ Nurse
3. ☐ Physician
4. ☐ Medical technician
5. ☐ Other *(Please specify:)* ______________
6. ☐ Do not know

6. How was the problem first discovered? *(Check one.)* (33)

1. ☐ In a preventative maintenance check
2. ☐ In a pre-application test
3. ☐ In clinical use
4. ☐ Other *(Please specify:)* ______________
5. ☐ Do not know

7a. In your opinion, which of the following describes the cause(s) of the problem? *(Check all that apply.)*

1. ☐ Defective components (34)
2. ☐ Improper labeling or instructions (35)
3. ☐ Improper use (i.e., misuse, user error, lack of training) (36)
4. ☐ Conditions of use (high tension or critical situation) (37)
5. ☐ Other user related factors (new therapeutic or surgical technique) (38)
6. ☐ Design flaw (39)
7. ☐ Design characteristic (40)
8. ☐ Wear or deterioration (41)
9. ☐ Packaging or sterilization problems (42)
10. ☐ Interaction(s) with other devices or drugs (43-44)
11. ☐ Service or maintenance problems (45-46)
12. ☐ Installation problems (47-48)
13. ☐ Product reuse or remanufacture (49-50)
14. ☐ Other *(Please specify:)* ______________ (51-52)
____
15. ☐ Do not know (53-54)

7b. If more than one response was checked in Question 7a, which do you consider to be the most important cause of the problem? *(Enter box number.)*

☐☐ (55-56)

8. Was any patient injury associated with the problem you reported? *(Check one.)* (57)

1. ☐ Yes *(Continue with Question 9.)*
2. ☐ No } *(Skip to Question 10.)*
3. ☐ Do not know }

9. Please describe the nature of the injury. (58-60)

____
____
____
____
____
____
____

10. In your opinion, could this problem have caused or contributed to serious injury or death? *(Check one.)* (61)

1. ☐ Yes
2. ☐ No
3. ☐ Do not know

11. In your opinion, if the problem were to recur, how serious an outcome could it cause or contribute to? *(Check one.)* (62)

1. ☐ Life threatening
2. ☐ Permanent impairment of body structure or function
3. ☐ Would require medical intervention to prevent impairment of body structure or function
4. ☐ Would require medical intervention to relieve temporary impairment of body structure or function
5. ☐ Minor injury or discomfort not requiring intervention
6. ☐ No adverse outcome
7. ☐ Do not know

12. Was any organization outside of the hospital contacted about the problem? *(Check one.)* (63)

1. ☐ Yes *(Continue with Question 13.)*
2. ☐ No } *(Skip to Question 16.)*
3. ☐ Do not know } *(Skip to Question 16.)*

13. The grid below lists a number of external organizations which may have been contacted regarding the problem associated with the medical device. Please indicate for each organization whether they were contacted, and, if so, the date and manner of the contact.

Organization	Organization Contacted *(Check one.)* Yes (1)	Organization Contacted *(Check one.)* No (2)	Date Contacted Enter Month/Day/Year	Type of Contact *(Check all that apply.)* Written (1)	Type of Contact *(Check all that apply.)* Oral (2)	
a. Device Manufacturer			/ /			(64-72)
b. Device Distributor			/ /			(73-81)
c. Food and Drug Administration			/ /			(82-90)
d. U.S. Pharmacopeia/ DEN			/ /			(91-99)
e. Emergency Care Research Institute (ECRI)			/ /			(100-108)
f. Other *(Specify.)* ________			/ /			(109-117)

14. For those organizations which were contacted about the problem, please describe their response(s) to the communication.

a. Device manufacturer ________________________ (118-119)
____
b. Device distributor ________________________ (120-121)
____
c. Food and Drug Administration ________________________ (122-123)
____
d. U.S. Pharmacopeia - Device Experience Network (DEN) ________________________ (124-125)
e. Emergency Care Research Institute (ECRI) (126-127)
____
f. Other *(Specify.)* ________________________ (128-129)
____

☐☐☐☐ ☐☐ 2

15. If the manufacturer was contacted about the problem associated with the medical device, with whom was the contact made?

(Check all that apply for each contact)

Contact	Main Office (1)	Regional Office (2)	
1. Distributor			(8-9)
2. Sales representative			(10-11)
3. Repair and service			(12-13)
4. Technical assistance			(14-15)
5. Management			(16-17)
6. Other *(Specify.)* ________			(18-19)

16. Besides contacting other agencies about the problem, was any action taken by the hospital in response to the problem? *(Check one.)* (20)

1. ☐ Yes *(Continue with Question 17.)*
2. ☐ No } *(Skip to Question 18.)*
3. ☐ Do not know } *(Skip to Question 18.)*

17. Which of the following actions were taken by the hospital in response to the problem? *(Check all that apply.)*

1. ☐ Inform hospital departments about the problem (21)
2. ☐ Repair or replace defective component (22)
3. ☐ Improve or institute in-service training program on proper use of device (23)
4. ☐ Label or relabel device (24)
5. ☐ Remove device from service (25)
6. ☐ Restrict use of device (26)
7. ☐ Other *(Please specify.)* ________________ (27)

The last series of questions is concerned with identifying **general** factors that may act as incentives to contact or not to contact the **manufacturer** of the device and the **Food and Drug Administration/U.S. Pharmacopeia - Device Experience Network-DEN**. The following questions do *not* only apply to the device for which you answered questions 1 through 17, but to **any** medical device.

18. How strong or weak are the following factors as incentives to contact the **manufacturer** concerning a problem with **any** device?

(Check one box for each factor.)

Factors	Very strong factor (1)	Strong factor (2)	Moderate factor (3)	Weak factor (4)	Very weak factor (5)	Not applicable (6)	
1. Ease of reporting							(28)
2. Device under service contract or warranty							(29)
3. Liklihood of receiving assistance from the manufacturer							(30)
4. Hospital policy to report all problems							(31)
5. As protection in case of litigation against the hospital							(32)
6. Because problem is serious							(33)
7. Need for service and repair of malfunctioning device							(34)
8. Other concerns *(Specify.)* ____________							(35)

19. How strong or weak are the following factors as incentives not to contact the **manufacturer** concerning a problem with **any** device?

(Check one box for each factor.)

Factors	Very strong factor (1)	Strong factor (2)	Moderate factor (3)	Weak factor (4)	Very weak factor (5)	Not applicable (6)	
1. Difficulty of reporting							(36)
2. Device *not* under service contract or warranty							(37)
3. Unliklihood of receiving assistance from the manufacturer							(38)
4. Hospital policy *not* to report problems							(39)
5. Concern about litigation against the hospital							(40)
6. Because problem is not serious							(41)
7. Problem is not related to device malfunction							(42)
8. Other concerns *(Specify.)* ____________							(43)

—4—

20. How strong or weak are the following factors as incentives to contact the **Food and Drug Administration**/U.S. **Pharmacopeia - DEN** concerning a problem with **any** device?

(Check one box for each factor.)

Factors	Very strong factor (1)	Strong factor (2)	Moderate factor (3)	Weak factor (4)	Very weak factor (5)	Not applicable (6)	
1. Ease of reporting	☐	☐	☐	☐	☐	☐	(44)
2. Liklihood of receiving a response from FDA/USP-DEN	☐	☐	☐	☐	☐	☐	(45)
3. Hospital policy to report all problems	☐	☐	☐	☐	☐	☐	(46)
4. As protection in case of litigation against the hospital	☐	☐	☐	☐	☐	☐	(47)
5. Because problem is serious	☐	☐	☐	☐	☐	☐	(48)
6. To exert pressure on the device manufacturer to rectify the problem	☐	☐	☐	☐	☐	☐	(49)
7. No satisfactory resolution of problem by manufacturer	☐	☐	☐	☐	☐	☐	(50)
8. Other concerns *(Specify.)* ______	☐	☐	☐	☐	☐	☐	(51)

21. How strong or weak are the following factors as incentives **not** to contact the **Food and Drug Administration/U.S. Pharmacopeia - DEN** concerning a problem with **any** device?

(Check one box for each factor.)

Factors	Very strong factor (1)	Strong factor (2)	Moderate factor (3)	Weak factor (4)	Very weak factor (5)	Not applicable (6)	
1. Difficulty of reporting	☐	☐	☐	☐	☐	☐	(52)
2. Unliklihood of receiving a response from FDA/USP-DEN	☐	☐	☐	☐	☐	☐	(53)
3. Hospital policy not to report problems	☐	☐	☐	☐	☐	☐	(54)
4. Concern about litigation against the hospital	☐	☐	☐	☐	☐	☐	(55)
5. Because problem is not serious	☐	☐	☐	☐	☐	☐	(56)
6. Unaware that I could report directly to FDA	☐	☐	☐	☐	☐	☐	(57)
7. Unware that I could report to the U.S. Pharmacopeia-DEN	☐	☐	☐	☐	☐	☐	(58)
8. Satisfactory resolution of problem by manufacturer	☐	☐	☐	☐	☐	☐	(59)
9. Other concerns *(Specify.)* ______	☐	☐	☐	☐	☐	☐	(60)

THANK YOU FOR YOUR HELP. PLEASE REMEMBER TO RETURN YOUR COMPLETED SURVEY IN THE ENCLOSED ADDRESSED ENVELOPE

—5—

Appendix IX

Our Methodology for Confirming Hospital Reports to Device Manufacturers and Independent Distributors

As we received each full hospital questionnaire, we logged it in and completed the lefthand side of the confirmation form from the information on the survey. (See appendix X.) This information included a description of the device with its type and model, the name of the manufacturer or independent distributor, the date the problem occurred, the date the problem was reported to the manufacturer or distributor, the verbatim hospital description of the problem, the name of the hospital, and, for most forms, the city where the hospital was located (coded as a "tracking number"). After the tracking information was entered, the form was filed alphabetically by the name of the contact—the hospital—and included in the next batch of forms to be mailed.

When we mailed the confirmation forms to the manufacturers and independent distributors, we included them in a packet sent to their chief executive officers by certified mail, return receipt requested. The packet contained the confirmation form, a description of the study and a request for the company's participation, a list of the 10 medical devices in our sample, a blank copy of the hospital questionnaire, and a return postcard enabling the company to request a copy of our report. The organizations were asked to complete the remainder of the confirmation form and return it to us in the envelope we provided. The form asked whether the transmittal had been located ("Was hospital contact located?") in the company's files, what the cause of the problem was, what actions the company had taken in response to the hospital's report of a problem, and whether the transmittal was registered in the company's good manufacturing practices complaint file.

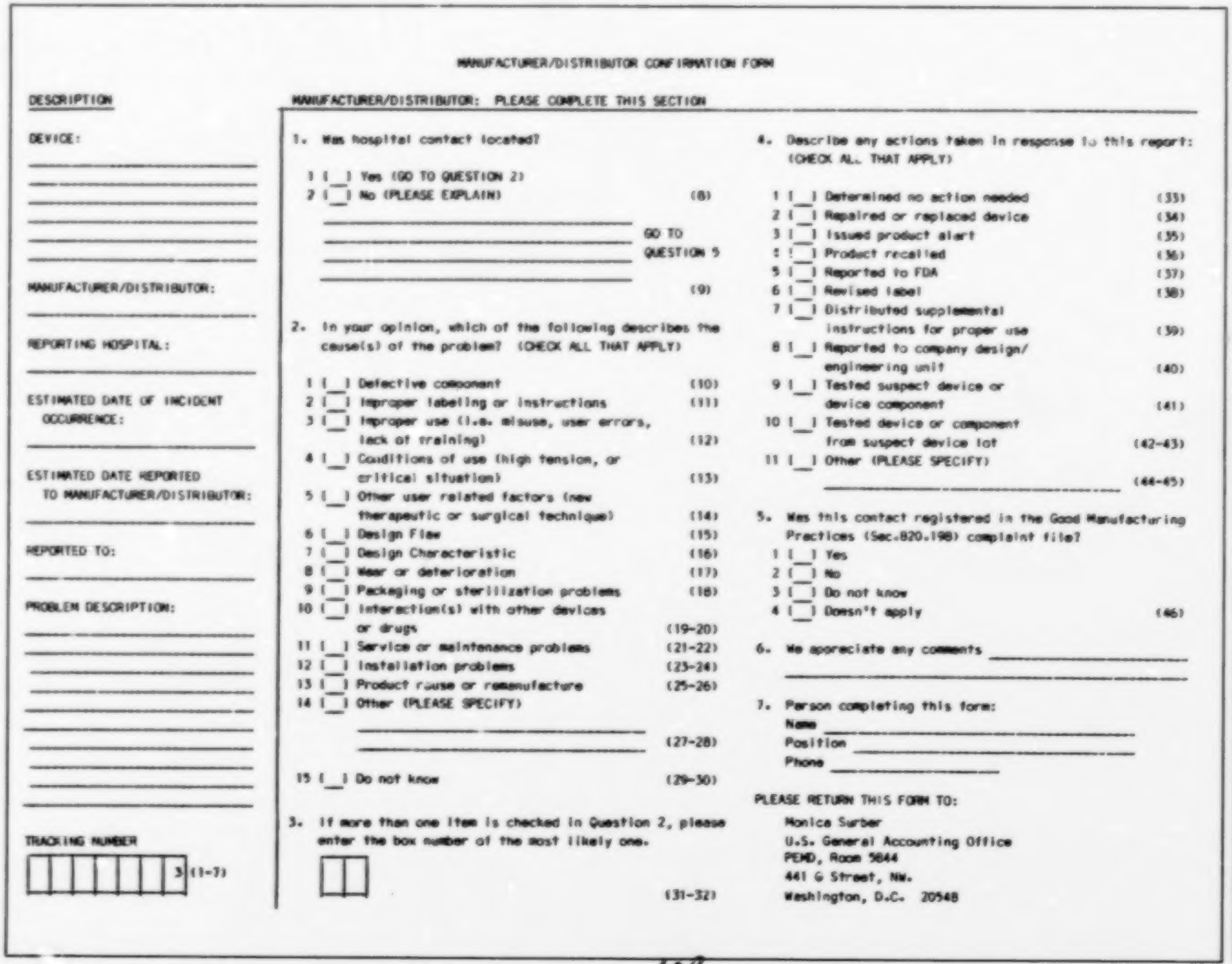
We used the same form for manufacturers and independent distributors. However, we changed the list of possible "actions taken" appropriately for the forms sent to FDA, the Emergency Care Research Institute, and third-party monitoring organizations. To FDA, we sent confirmation forms for both direct hospital transmittals to the agency and transmittals the hospitals sent through the device experience network. Confirmation forms were not sent to "other" contact points indicated, such as other units in the hospitals, other hospitals, or vaguely named organizations such as "insurance company," "electronics communications firm," and "parts vendor."

FDA provided us with a list of manufacturers and their addresses for the firms that produced at least 1 of the 10 devices. We obtained the names of chief executive officers from the Medical Device Registry and by calling the companies. For independent distributors that were not listed in the Medical Device Registry, we contacted the hospitals again in order to obtain an independent distributor's address and chief executive officer. In many of these instances, the hospitals did not know this information, and we had to make phone calls to the independent distributors for the names and addresses. When we could not obtain any address for the independent distributor but could identify the device manufacturer, we mailed the confirmation form to the manufacturer. Seventy-six percent of the distributors that were mailed confirmation forms were the same organization as the product manufacturer.

We mailed a total of 226 forms (actual number, unweighted), and we received 181 completed forms in return, a response rate of 80 percent. Of the 86 separate companies that we mailed confirmation forms to, 58 returned the form, a response rate of 67 percent.

During telephone follow-ups asking for the return of the form, we asked the companies to describe their product distribution and repair practices and how they determined whether or not the information from the hospital transmittal would reach the manufacturer's main office.

Our Confirmation Form for Manufacturers and Independent Distributors



MANUFACTURER/DISTRIBUTOR CONFIRMATION FORM

DESCRIPTION

DEVICE: ____________________

MANUFACTURER/DISTRIBUTOR: ____________________

REPORTING HOSPITAL: ____________________

ESTIMATED DATE OF INCIDENT OCCURRENCE: ____________________

ESTIMATED DATE REPORTED TO MANUFACTURER/DISTRIBUTOR: ____________________

REPORTED TO: ____________________

PROBLEM DESCRIPTION: ____________________

TRACKING NUMBER ☐☐☐☐☐☐ 3 (1-7)

MANUFACTURER/DISTRIBUTOR: PLEASE COMPLETE THIS SECTION

1. Was hospital contact located?

1 ☐ Yes (GO TO QUESTION 2)
2 ☐ No (PLEASE EXPLAIN) (8)
____________________ GO TO QUESTION 5 (9)

2. In your opinion, which of the following describes the cause(s) of the problem? (CHECK ALL THAT APPLY)

1 ☐ Defective component (10)
2 ☐ Improper labeling or instructions (11)
3 ☐ Improper use (i.e. misuse, user errors, lack of training) (12)
4 ☐ Conditions of use (high tension, or critical situation) (13)
5 ☐ Other user related factors (new therapeutic or surgical technique) (14)
6 ☐ Design Flaw (15)
7 ☐ Design Characteristic (16)
8 ☐ Wear or deterioration (17)
9 ☐ Packaging or sterilization problems (18)
10 ☐ Interaction(s) with other devices or drugs (19-20)
11 ☐ Service or maintenance problems (21-22)
12 ☐ Installation problems (23-24)
13 ☐ Product reuse or remanufacture (25-26)
14 ☐ Other (PLEASE SPECIFY) ____________________ (27-28)
15 ☐ Do not know (29-30)

3. If more than one item is checked in Question 2, please enter the box number of the most likely one.

☐☐ (31-32)

4. Describe any actions taken in response to this report: (CHECK ALL THAT APPLY)

1 ☐ Determined no action needed (33)
2 ☐ Repaired or replaced device (34)
3 ☐ Issued product alert (35)
4 ☐ Product recalled (36)
5 ☐ Reported to FDA (37)
6 ☐ Revised label (38)
7 ☐ Distributed supplemental instructions for proper use (39)
8 ☐ Reported to company design/engineering unit (40)
9 ☐ Tested suspect device or device component (41)
10 ☐ Tested device or component from suspect device lot (42-43)
11 ☐ Other (PLEASE SPECIFY) ____________________ (44-45)

5. Was this contact registered in the Good Manufacturing Practices (Sec.820.198) complaint file?

1 ☐ Yes
2 ☐ No
3 ☐ Do not know
4 ☐ Doesn't apply (46)

6. We appreciate any comments ____________________

7. Person completing this form:

Name ____________________
Position ____________________
Phone ____________________

PLEASE RETURN THIS FORM TO:

Monica Surber
U.S. General Accounting Office
PEMD, Room 5844
441 G Street, NW.
Washington, D.C. 20548

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Our Methodology for Objective 3 and the 15 Hazard-Monitoring Systems We Reviewed

Our understanding of the structure and operation of the 15 systems besides FDA's for monitoring hazardous technologies was based on our review of the agencies' enabling legislation, promulgated regulations, program documentation, independent evaluations, and interviews with program managers and staff. These data formed the basis for our analysis of their methods and determination of whether their practices are promising for FDA's use. The criterion we used in determining this was the extent to which we thought the practices could attenuate the problems we found—especially the problem of underreporting—in the FDA's current postmarketing surveillance system. In this way, we hoped to suggest ways of improving the communications network's quality and usefulness as a management tool for FDA and as an early warning system for the public, to prevent multiple injuries associated with the use of medical devices. The 15 systems we reviewed and their agencies are listed below.

Consumer Product Safety Commission

National Electronic Injury Surveillance System

Department of Labor

Mine Safety and Health Administration, Mine Accident, Injury, and Illness Report System

Occupational Safety and Health Administration, Bureau of Labor Statistics, Annual Survey of Occupational Injuries and Illnesses/Supplementary Data System

Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, National Occupational Exposure Survey

Department of Transportation

Coast Guard, National Response Center

Coast Guard, Recreational Boating Accident Reporting System

Federal Aviation Administration, Airline Consumer Complaint Information System

Federal Aviation Administration, Near Mid-Air Collision Reporting System

Federal Aviation Administration, Service Difficulty Reporting System

Federal Aviation Administration, National Aeronautics and Space Administration, Aviation Safety Reporting System

Federal Railroad Administration, Railroad Accident Incident Reporting System

National Highway Traffic Safety Administration, Fatal Accident Reporting System

National Highway Traffic Safety Administration, National Accident Sampling System

Environmental Protection Agency

National Emissions Data System

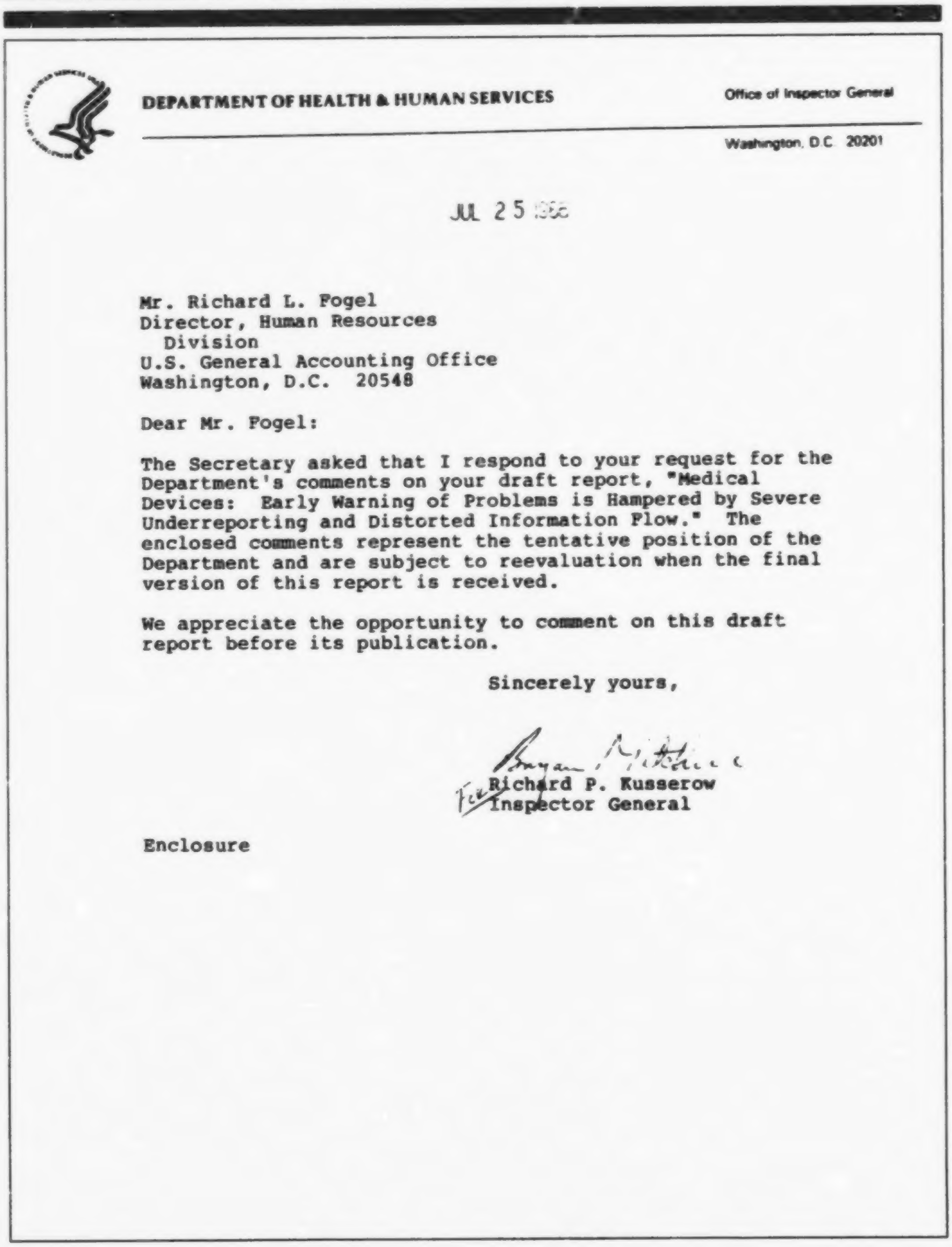
Nuclear Regulatory Commission

Licensee Event Report System

Appendix XII

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUL 25 1986

Mr. Richard L. Fogel
Director, Human Resources
Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report, "Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting and Distorted Information Flow." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Bryan Mitchell
Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "MEDICAL DEVICES: EARLY WARNING OF PROBLEMS IS HAMPERED BY SEVERE UNDERREPORTING AND DISTORTED INFORMATION FLOW," DATED JUNE 1986

General Comments

We appreciate the opportunity to comment on the draft report. We find the report to be generally good, providing a valuable baseline analysis of adverse-event reporting prior to initiation of the Medical Devices Reporting (MDR) program. It will enhance future evaluations of the impact of the MDR program.

We do, however, have some suggestions for improving the quality of the report:

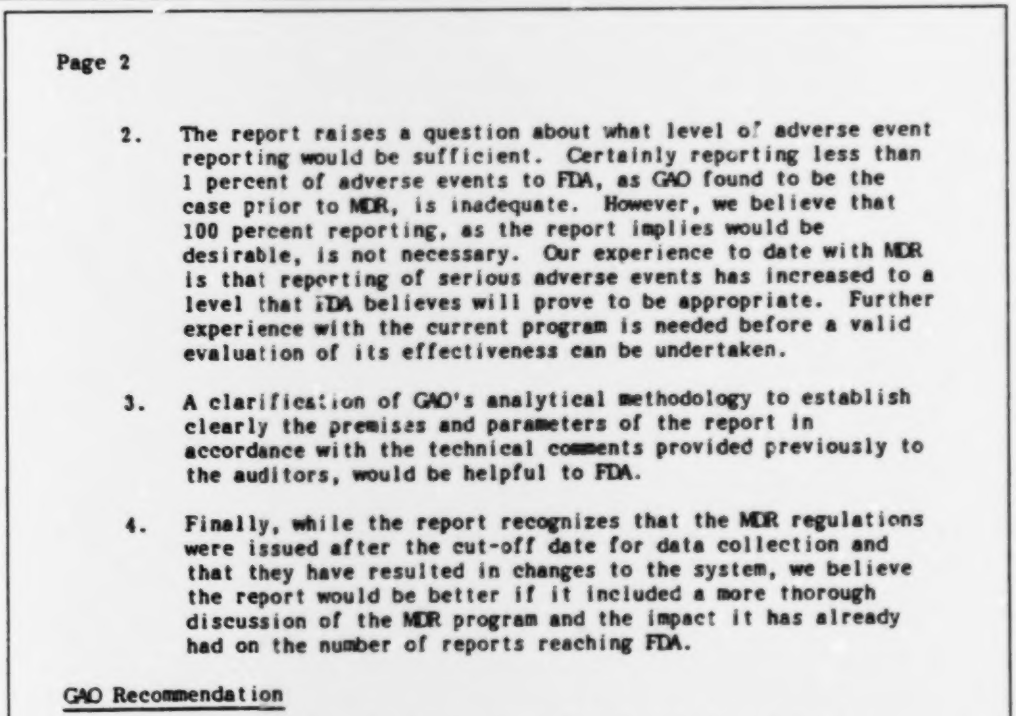
1. Chapter 2 - which deals with the Food and Drug Administration's (FDA) mechanisms for allowing new devices to reach the marketplace - is basically incorrect. For example, the report includes a "hybrid" 510(k) as one means to gain FDA approval of a new device. FDA does not provide such a mechanism to the industry.

   Another example is the inclusion of Investigational Device Exemptions (IDEs) as a means for marketing new devices. In fact, IDEs are a means for allowing manufacturers to do the clinical research necessary for marketing without being in violation of the law. It is not intended - nor permitted - that devices under IDEs are available for use outside the clinical research setting.

   See comment 1.

   The report is not dependent upon Chapter 2 to support its thesis. Therefore, we suggest that the entire Chapter be deleted on the basis that it misstates the device approval processes and implies that postmarketing surveillance of devices is necessary because possibly unsafe, ineffective devices are allowed to be marketed. Actually, a postmarketing surveillance system is necessary irrespective of the review and approval processes in FDA. No device can be so thoroughly tested as to absolutely rule out occurrence of unexpected adverse events after its general distribution. The intent of the MDR regulations is to gather information about actual experience with devices once they are in general use to assure that public health protection is adequate.

   If GAO decides that Chapter 2 is necessary, we believe it would be necessary for GAO to carefully reexamine it in accordance with the marked-up copy of the draft FDA provided to them in order to eliminate factual and legal inaccuracies.



Page 2

See comment 2.

2. The report raises a question about what level of adverse event reporting would be sufficient. Certainly reporting less than 1 percent of adverse events to FDA, as GAO found to be the case prior to MDR, is inadequate. However, we believe that 100 percent reporting, as the report implies would be desirable, is not necessary. Our experience to date with MDR is that reporting of serious adverse events has increased to a level that FDA believes will prove to be appropriate. Further experience with the current program is needed before a valid evaluation of its effectiveness can be undertaken.

See comment 3.

3. A clarification of GAO's analytical methodology to establish clearly the premises and parameters of the report in accordance with the technical comments provided previously to the auditors, would be helpful to FDA.

See comment 4.

4. Finally, while the report recognizes that the MDR regulations were issued after the cut-off date for data collection and that they have resulted in changes to the system, we believe the report would be better if it included a more thorough discussion of the MDR program and the impact it has already had on the number of reports reaching FDA.

GAO Recommendation

The GAO recommends that the Secretary of Health and Human Services:

1) --Require that all independent distributors of medical devices report to device manufacturers as manufacturers are required to report to FDA under the medical devices reporting rule.

See comment 5.

Department Comment

In drafting the MDR regulations, FDA considered requiring reports from medical devices distributors. It was decided, however, that the agency should have some experience with manufacturers' reporting before deciding whether to extend the requirements of MDR to others in the device distribution chain. Our experience to date indicates that it may not be necessary to do so. FDA will continue to evaluate the MDR program and propose changes should it become necessary.

GAO Recommendation

2) --Investigate the feasibility of changing FDA's system for postmarketing surveillance to include systematic but voluntary reporting of device problems, by a representative sample of hospitals, directly to the device manufacturers. The manufacturers would then report to FDA in accordance with the medical device reporting rule.

Page 3

See comment 6.

Department Comment

The intent of this recommendation - getting hospitals to report adverse events - is certainly in keeping with FDA's goal. The specific approach recommended, however, is problematic. FDA considered many different approaches to acquiring reports of device problems, including the 1980 demonstration using two hospitals under contract to collect adverse event data mentioned by GAO. The system was never fully implemented for several reasons, including reluctance of hospitals to participate and lack of resources to continue and expand the system.

As stated in our general comments, an adequate reporting system might not include receiving reports of all adverse events or device problems (most of which do not lead to an adverse event insofar as the patient is concerned). The intent of the device reporting system is to provide FDA with sufficient information to make appropriate postmarketing regulatory decisions, which could range from merely observing the performance of a particular device to requiring that the device be withdrawn from the market. We expect that most devices will require no postmarketing action by FDA.

Designing and implementing a system that will give FDA the needed information without overburdening hospitals, distributors, manufacturers, or FDA requires resolution of some very fundamental issues such as:

1. What level of reporting will be sufficient to provide FDA the information it needs?

   The level of reporting required directly affects the cost of implementing and maintaining the system for all parties. It also determined how systems are designed and what degree of follow-up would be required.

2. How would hospitals be selected to participate in the program?

3. Would selected hospitals be adversely impacted by becoming identified as "problem" hospitals?

4. How would inclusion as a reporting hospital affect hospital and professional liability?

   This is a major factor in the willingness of hospitals/health care professionals to cooperate in a voluntary reporting system.

5. How do we overcome the reluctance of hospitals to report problems and adverse events, either indirectly through the manufacturers or directly to FDA?

Page 4

See comment 7.

6. How would such a system be financed?

It is very costly to implement and operate an effective adverse event reporting system for all parties. Hospitals/health professionals must take professional time from other duties or, if warranted, hire extra help to prepare reports. Manufacturers would need staff to handle the reports, and so would FDA. As mentioned above, the 1980 demonstration that was financed through FDA contracts with the two hospitals did not develop into a complete system in part because of competing priorities. With the current need to be especially mindful of how Federal funds are expended, we are particularly concerned that any reporting system, voluntary or mandatory, be cost effective.

Notwithstanding the constraints identified above and the complexity of designing a valid system, FDA is committed to pursuing the best reporting system possible at a reasonable cost. We believe the MDR gives us a very good start in that direction and, coupled with the recent requirement initiated by the Joint Commission on the Accreditation of Hospitals that accredited hospitals maintain records on adverse medical device related events, may be sufficient for public health protection. FDA will assess the sufficiency of the current program when there has been enough experience to allow a valid analysis and determine what further actions should be taken.

GAO Recommendation

3) --Establish cooperative relationships with professional health organizations to develop and distribute educational materials for health care professionals on FDA's need for early warning information and on how to report medical devices problems.

See comment 8.

Department Comments

FDA has a well-established cooperative program with medical devices manufacturers and health professionals who use devices based upon our belief in the effectiveness of educational efforts for solving problems. FDA has undertaken extensive and costly efforts to publicize the existence of the program and our need for information. We were, therefore, dismayed that the report revealed such a general lack of awareness of the program among health care professionals. FDA is now looking for other ways to reach health care professionals with this information and to encourage their participation, bearing in mind the limited resources available to pursue educational programs. Since this problem has just come to the Agency's attention, we cannot provide a specific course of action that will be taken.

The following are GAO's comments on the Department of Health and Human Services' letter dated July 25, 1986.

GAO Comments

1. We concur with HHS that a device cannot be so thoroughly tested as to rule out absolutely adverse events after its release for general distribution, which underscores the need for and importance of a flow of postmarketing information to FDA. However, we also believe that it is important to understand all the processes that are involved in protecting the public health with regard to the safety and effectiveness of devices. We believe that chapter 2 is an integral part of our study and provides a necessary context for our review of postmarketing surveillance activities. In fact, congressional concerns about the integrity of the premarketing notification process were significant enough that we were subsequently requested by the Congress to evaluate the 510(k) process. This evaluation will be presented in a separate report. We revised chapter 2 in accordance with the marked-up copy of the draft report provided by FDA.

2. Our report was not meant to imply that 100-percent reporting was necessary for the agency to be able to make appropriate postmarketing regulatory decisions. We believe that the agency is best able to determine the level of reporting that it requires in order to establish the nature and scope of problems related to medical devices. We agree that the reporting of serious events, such as those described in the medical-device reporting rule, are the most important. The rule requires that manufacturers and importers of medical devices report to FDA when they become aware of serious problems associated with their devices, and the reporting of serious adverse events may have increased as a result of the rule. However, we found in our study that the more serious events were the least likely to be reported outside the hospitals. For example, among the unreported incidents uncovered in our study was one that involved the death of a patient. This gap in the flow of information raises serious questions about the nature and scope of problems that can be identified by the regulation, and we draw the attention of HHS analysts to the need to rethink this issue.

3. The methodological questions FDA is concerned about focus on the analysis and interpretation of the data derived from the study's first-wave questionnaire (the screening survey) and the relationship between this questionnaire and the analysis and interpretation of the data derived from the study's second-wave questionnaire (the full hospital survey). In response to FDA's comment, we have expanded our discussion

of the screening survey, in chapter 3 and appendix V, to further clarify the study's methodology and the relationship between the two questionnaires.

4. As we indicated in comment 2, we expect that the implementation of the medical-device reporting rule will increase the number of reports that are sent to FDA. Since our study did not include an evaluation of the rule, we are not able to definitively assess its effect. We do, however, expect to do a follow-up study that will include a review of the rule, and we have included a description of the purpose and operation of the rule in chapter 2. (See page 36.)

5. The medical-device reporting rule does not currently require reporting by independent distributors of medical devices. Our findings show that distributors are a link in the communications systems, that they are notified of the occurrence of problems, and that often they do not transmit this information to manufacturers or FDA. This information supports the need to include them in the mandatory reporting scheme, as indicated in sections 26a and 26b of the final rule.

6. Since the agency reviewed the draft report, this recommendation has been revised and is now shown as number 3.

7. We concur with HHS that the issues it poses are among those that should be addressed, through an empirical study, before implementing an enhanced reporting system. This is precisely why we recommend that HHS explore the possibility of changing FDA's system for postmarketing surveillance to include the systematic but voluntary reporting of problems with devices, by a representative sample of hospitals, directly to the device manufacturers. We recognize that there are some obstacles to be overcome in doing this, and we believe that a strong study by FDA will go a long way toward reducing them. We also note that FDA's prior experience was in 1980 and that many attitudes in the hospital community have changed since then. For example, we were told when we started our study that we would not get much help from hospitals. Instead, cooperation by hospitals turned out to be exemplary, and our response rate of 81 percent reflects this cooperation.

8. We recognize that FDA has undertaken extensive and costly efforts to publicize the problem-reporting program and that it needs information. What is needed, along with the recognition that FDA's effort does not seem to be working well, is an examination of the implementation of the

effort, in order to determine why awareness of the program is so low among health-care professionals. (See page 35.)

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Glossary

Chi Square	A test of statistical significance to determine whether there is a systematic relationship between two variables. By itself, chi square indicates whether variables are independent or related. It does not indicate how strongly they are related.
Class I	One of three regulatory classes set up by the Medical Device Amendments of 1976 (Public Law 94-295) and defined in 21 C.F.R. 860.3(c)(1)-(3). Class I, general controls, contains devices for which general controls authorized by the act are sufficient to provide a reasonable assurance of safety and effectiveness. Manufacturers of class I devices must, among other things, register their establishments, list their devices with FDA, notify FDA 90 days before marketing a device, and conform to good manufacturing practices. See also Class II, Class III.
Class II	A regulatory class of devices for which general controls are insufficient to provide a reasonable assurance of safety and effectiveness and scientific information is sufficient to establish performance standards to provide such assurances. The general controls provisions for class I devices under the Medical Device Amendments of 1976 apply also to class II devices. See also Class I.
Class III	A regulatory class of devices for which general controls are insufficient to ensure safety and effectiveness, scientific information does not exist to establish performance standards, and the device supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury. The general controls provisions for class I devices under the Medical Device Amendments of 1976 apply also to class III devices. See also Class I.
Device Type	All products of a particular type or group of separate types that are similar. FDA classifies device types according to the potential risk posed by their use and the degree of regulation they require. The full definition is in 21 C.F.R. 860.3(i).
Good Manufacturing Practices	Requirements applicable to all three regulatory classes of devices for their manufacturing, packaging, storage, and installation, according to regulations promulgated under the Medical Device Amendments of 1976.

Investigational Device Exemption	A regulatory category and process under which FDA permits the limited use of an unapproved medical device in controlled settings for the purpose of collecting data on safety and effectiveness that may be used in support of a premarketing approval application.
Medical Device	Any instrument, apparatus, implement, machine contrivance, implant, in vitro reagent, or similar or related article that is intended to help diagnose a disease or its conditions; to prevent, diagnose, mitigate, or treat a disease; or to affect the structure or function of the body. A medical device does not achieve any of its principal intended purposes through chemical action within or on the human body or the bodies of other animals, and it does not depend on being metabolized in order to achieve any of its principal intended purposes. The full definition is in U.S.C. 321(h).
Orphan Product	A drug or medical device for rare diseases or conditions. The full definition is in the Orphan Drug Act of 1983 (Public Law 97-414).
Postamendments Device	A medical device first marketed on or after May 28, 1976, when the Medical Device Amendments of 1976 became effectve.
Preamendments Device	A medical device marketed before May 28, 1976, when the Medical Device Amendments of 1976 became effective.
Premarketing, or Premarket, Approval Application (PMAA)	An application to FDA for approval to market a new or transitional device. The sponsor of the device must submit information to FDA that documents the safety and effectiveness of the device before it may be marketed.
Premarketing, or Premarket, Notification	A manufacturer's notification of FDA of the intention to market a device. From the information the manufacturer supplies in its document, FDA determines whether the device is substantially equivalent to a preamendments or reclassified device. In general, a device that is substantially equivalent may be marketed without premarketing approval or reclassification into class I or II. A device that is not substantially equivalent remains in class III as a new device and may not be marketed without such approval or reclassification.

Substantially Equivalent Device	A device first marketed after the Medical Device Amendments of 1976 that FDA has found to be similar to a preamendments device because it has the same intended use and does not differ markedly in materials, design, or energy source, although it need not be identical to a preamendments device.
Tau B and Tau C	Measures of the strength of association, ranging from +1 to −1, between two variables. The measures indicate the proportional reduction in error made when predicting a dependent variable when the values of an independent variable are known. Tau B is the more appropriate for square tables, in which the number of rows equals the number of columns; tau C is the more appropriate for rectangular tables.
Transitional Device	A device that was regulated as a new drug before the enactment of the Medical Device Amendments of 1976.

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